

SCIENTIFIC CONSIDERATIONS OF OLESTRA AS A FAT SUBSTITUTE

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Olestra is, a sucrose polyester, a noncaloric fat substitute, made from sucrose and several fatty acid esters. It has been approved by the FDA as a food additive used in preparing low-fat deep-frying foods such as savory snacks. Available literature on olestra was evaluated that had both positive and negative connotations. Clinical trials in numerous species of animals including humans were conducted to determine if olestra would affect the utilization and absorption of macro- and micronutrients; the effects of olestra on growth, reproduction, or its toxicity were also examined. The roles of olestra as a fat substitute, how it could effect on humans and the environment, and the potential impacts from its use in large amounts were assessed. Olestra can be removed from the environment by aerobic bacteria and fungi which may be isolated from activated sludge and soils.

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## INTRODUCTION

### 1.1 Historical background of olestra.

In the last few decades, Public Health authorities have shown concern over the long-term health consequences of diets with a high fat content. Organizations such as the American Heart Association and the American Dietetic Association continuously suggest in editorials, feature stories, and news reports that fat consumption be reduced in order to avoid cardiac and other problems. Although many individuals are becoming more health conscious, life-long eating habits are difficult to change. Repeated warnings that a diet high in fats is not commensurate with good health go largely unheeded as of 1999. One explanation for this, simply put, points strongly at the fact that human beings enjoy the taste, the texture, and the “mouth feel” of fatty foods.

At the same time that various agencies and almost all medical organizations warn about the dangers of excessive fat consumption, they must also point out that a certain amount of fat is essential to good health and, therefore, the diet must contain that certain amount of fatty substances. Fats in the diet serve as major sources of energy, as essential components of cellular membranes, and as carrier molecules that transport many essential water-insoluble vitamins in the blood and other body fluids. In addition, certain fats, specifically those that contain polyunsaturated fatty acids, such as  $\alpha$ -linolenic acid play

important roles in cellular homeostasis. Since many fats that contain polyunsaturated fatty acids are not synthesized in the human body, these must be acquired from dietary sources (Werner, 1992). In general, lack of such substances leads to impaired cellular activity and may even lead to overt medical complications.

Obesity, a serious medical syndrome, is often the result of over-consumption of fats since the energy content of fats is greater on a weight basis than that of any other food substance. For example, each gram of fat contains approximately nine kilo-calories (kcal) of available energy. By comparison, the same weight in carbohydrates and proteins each contain approximately four kcal of available energy (Dietary Guidelines for Americans: U.S. Department of Agriculture and U.S. Department of Health and Human Services, 1990). Large amounts of fat in the normal diet lead to excessive amounts of energy that, if not used, are stored in the human body as body fat. The resultant obesity is closely associated with increased risks of coronary heart disease, stroke, hypertension, certain forms of cancer (breast and colon cancers), diabetes, and lipid disorders (Mayo Clinic Health Letter, 1998). Responding to these concerns, the United States Department of Agriculture and the Department of Health and Human Services (USDA/ US DHHS, 1990) issued a recommendation in 1985 that Americans lower the percentage of total energy from fat in the typical diet from the current figure of 36% of total caloric intake to a suggested value of 30% or less (Morrison and Putnam, 1991; US DHHS, 1990; David, 1997). Furthermore, the studies of the United States Department of Health and Human Services (Public Health Service, 1991) indicated that a high proportion of fat in the typical American diet is from fat that contains saturated fatty acids. The typical



American diet contains as much as 16% of total energy in the form of saturated fatty acids whereas only 7-10% is recommended.

Other agencies such as the U.S. Department of Health and Human Services (1990) and the National Cholesterol Education Program (1988) recommend that the well balanced diet contain approximately 200 to 300 mg of cholesterol per day. Cholesterol is considered a non-fatty acid fat by scientists and medical authorities. Limitation of the amount of ingested cholesterol is a point of strong concern since many studies have shown that a strong link exists between the detrimental effects of low density lipoprotein (LDL) and diets high in both cholesterol and fats with saturated fatty acids. The combination is considered a strong predictive factor of heart disease by the U.S. Department of Health and Human Services in 1988.

Although the facts stated above have been known for many years, recent data suggest that American dietary habits have not changed in favor of lower fat ingestion but, in fact, that the reverse is true. In 1998, the American Heart Association (see Harvard Health Letter, 1998) estimated that 55% of the American public was overweight and that this represents a two-fold increase from 1990 when the number of obese individuals constituted only 26% of the population. Even now, the trend is upward with respect to higher LDL and higher dietary cholesterol and saturated fatty acid fats.

Surveys were conducted in 1975 for the link between the amount of fat intake and prostate cancer. The survey results showed that the estimated amount of fat that the Americans and most of the Europeans consumed in diets was in the range from 130 to 160 grams per day. The estimated amount of fat intake for Southeast Asians was in the

range from 30 to 50 grams per day while South Americans in the range from 50 to 100 grams per day. As shown in Figure 1, higher fat intake caused higher death rates due to prostate cancer. As a consequence of high amounts of fat in their diet, Americans and most Europeans have a much higher death rate due to prostate cancer than South Americans and Southeast Asians.

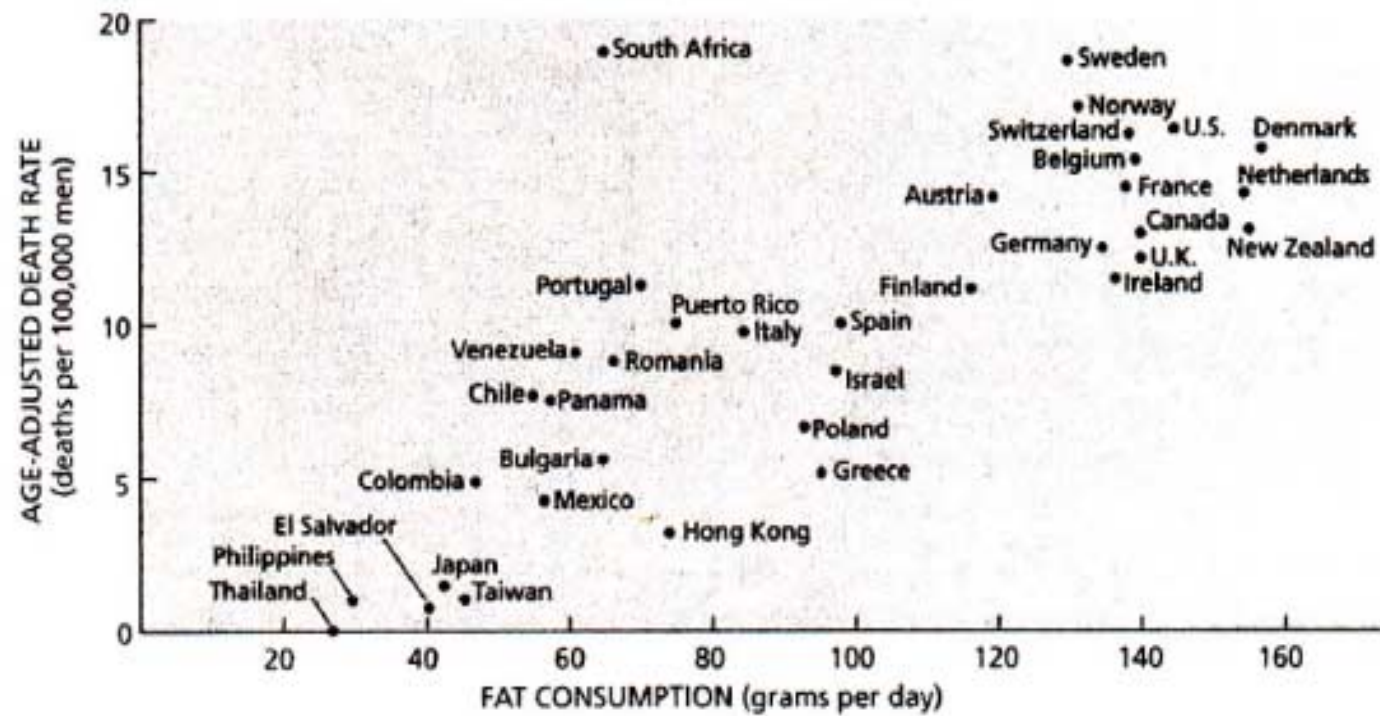


Figure 1. A link between diet and prostate cancer (Carroll and Khor, 1975) p. 10.

In attempts to address the health concerns attributed to excessive fat in the diet and the growing Public Health interest in achieving and maintaining optimum body weight, food manufacturers look for ways of producing and introducing tasteful foods with low fat content. One approach is to reduce the amount of fat in food products by adding ingredients that mimic the taste and the “mouth-feel” of fat. Another approach is to develop fat derivatives or fat substitutes using novel compounds that simulate the texture and flavor of fats commonly found in foods but that are not absorbed from the intestinal tract with the result that the total calorie yield of the food is substantially reduced (Swanson and Akoh, 1994). In other words, one strategy for reducing fats as components of the average American diet is to replace fats with non-fat substances while the other depends on using fats or fat-like substances that are not absorbed into the body (Hamm, 1984). Unfortunately both approaches have so far led only to products of inferior quality and increased cost. For purposes of studying fat replacements in food, fat substitutes have been divided into two categories (Mattson, *et al.*, 1971). Fat mimetics are compounds that mimic the taste and texture of fat while fat substitutes are compounds that physically and chemically resemble natural fats but are somehow prevented from delivering their energy content to the body. In general, the former cannot be used as fat replacements on an equal weight basis and they are not stable when heated. The latter are stable at cooking and frying temperatures and can replace fats on an equal weight basis (Calorie Control Council, 1991; cited in Swanson and Akoh, 1994).

In general, the recognized strategy for developing a poorly digested, or a nondigestible and/or non-absorbable fat is to chemically alter or to synthesize a natural

fat (i. e., a glycerol moiety attached through ester bonds to three fatty acids = triglyceride) in order to alter its susceptibility to hydrolysis and/or absorption from the intestinal lumen. At the same time, the product should retain its taste, texture, and mouth-feel so that the food prepared from it may taste as if it contained the appropriate quantity of natural fat. Suggested design strategies for fat replacements include the following.

1. Replacing the glycerol moiety of a triglyceride with alternative sugars or polyols.
2. Replacing the fatty acids with alternative acids (steric protection of the ester bond branched carboxylic acid esters of glycerol).
3. Reversing ester linkages, i.e., replace the glycerol moiety with a polycarboxylic acid, amino acid or other poly functional acid and esterify with a suitable long chain alcohol.
4. Reducing the ester linkage of the glycerol moiety to an ether linkage (Hamm, 1984; Singhal *et al*, 1991; cited in Swanson and Akoh, 1994).

The chemical (molecule) design of a product owned by Procter & Gamble named olean, with the trade name of olestra, possesses functional properties comparable to those of a natural lipid. Use of this product in many foods has so far yielded a substance of low caloric value and high market acceptability. Because olestra is made of long-chain fatty acids, its physical properties are like those of natural fats and, like fats, it can be heated without altering its chemical structure. Also, olestra gives food the same texture and aroma as does of fat. Its most desirable property is that this large, bulky lipid is not hydrolyzed by intestinal lipases and it does not enter the mixed micellar phase in the

intestinal lumen. All preliminary studies indicate that it is not absorbed from the intestinal tract and that it does not contribute calories to the diet (Bergholz, 1992b).

It is claimed that olestra is a non-caloric fat substitute and that it ushers in a new era for fat-free cooking. Two scientists with Procter & Gamble, Fred H. Mattson and Robert A. Volpenhein, discovered olestra serendipitously in 1968 while studying fat digestion. They accidentally synthesized a molecule in which sucrose was esterified with several fatty esters (a polyester) while trying to find sources of fatty acids other than those that occurs naturally in milk for the diets of premature infants. At present, Procter & Gamble manufacture olestra on a commercial scale and sell it primarily for use in snack foods.

Chemists first described fatty acids esterified to sucrose a century prior to the development of olestra (Wei, 1984; cited in Swanson and Akoh, 1994) while others examined the physical properties of esterified fatty acid-sucrose molecules (Hass, 1977; cited in Swanson and Akoh, 1994). Still others found ways of synthesizing these compounds in an efficient manner suitable for commercial purposes (Rizzi and Taylor, 1978).

In 1952, a patent was issued for work on fatty acid transesterification of polyhydroxyol groups of compounds such as sucrose in the solvent dimethylformamide (Hass, 1977). This opened the door for the possibility of synthesizing novel sugar derivatives. Sucrose fatty acid esters consisting of mono- and di-esters were first developed by Foster D. Snell, Inc. in consultation with the Sugar Research Foundation (Wei, 1984). Esterification of lipophilic fatty acids to the hydrophilic sugar resulted in a

molecule with lipophilic and hydrophilic surface-active functionality (Swanson and Akoh, 1994). The number of mono- to octa- fatty acid substitutions on sucrose in a reaction mixture determined the lipophilic or hydrophilic character of the product molecules. The degree of esterification was defined by the number of hydroxyl groups of the sugar that were esterified with the carboxylic groups of the fatty acids. By controlling the degree of esterification to mono-, di-, and triesters, the sucrose fatty acid polyester functional properties could be predicted according to the hydrophilic-lipophilic balance values adopted for food emulsifiers (Akoh, 1994a; Wei, 1984; cited in Swanson and Akoh, 1994).

During the 1960s, scientists in the development and research department at Procter & Gamble discovered a unique sucrose polyester that resisted digestion by pancreatic lipase (Mattson *et al.*, 1971), an intestinal enzyme important in fat digestion that is specific for the hydrolysis of ester bonds. Procter & Gamble obtained a patent for this enzyme in 1970 which gave the company exclusive use of all sucrose polyesters (Mattson *et al.*, 1971). Following successful preliminary human studies in 1975, Procter & Gamble petitioned the U.S. Food and Drug Administration (FDA) for use of olestra as a cholesterol-lowering drug in addition to its use as a fat replacement as described in other patents. In 1987, Procter & Gamble submitted a petition for the approval of olestra as a calorie-free replacement for fat in shortening and cooking oil (Giese, 1996; Shikles, 1992). In this petition, Procter & Gamble requested that olestra be used as a replacement for up to 35% of the fat in cooking oils and shortenings for home use, and for up to 75% of the fat used in commercial deep-fryers for snack foods. However, Procter & Gamble

failed to identify specific uses to sufficiently support their claim and failed to obtain the permission they requested. Part of the reason they were denied permission was the fact that they failed to provide significant answers to many questions posed by the FDA during the review process. Procter & Gamble withdrew their petition in 1987 (Giese, 1996; Shikles, 1992) and in 1988, after it was determined that olestra did not sufficiently lower cholesterol levels, they also withdrew the application submitted in 1975.

Since 1987, the focus at Procter & Gamble has been to modify the chemical structure of olestra so that the physical and chemical properties of the product are more as those of natural fats. In 1990, in order to satisfy certain FDA requirements, Procter & Gamble amended their petition and asked to only be permitted to use olestra as a replacement for natural fats in the preparation of snack foods such as cheese puffs, crackers, and potato chips (Giese, 1996; Shikles, 1992). They did not ask for permission to use it as a general household and commercial fat. Approval of olestra by the FDA in 1996 resulted in the use of this fat substitute in familiar snack foods such as crackers and potato chips (Klis, 1996; Giese, 1996).

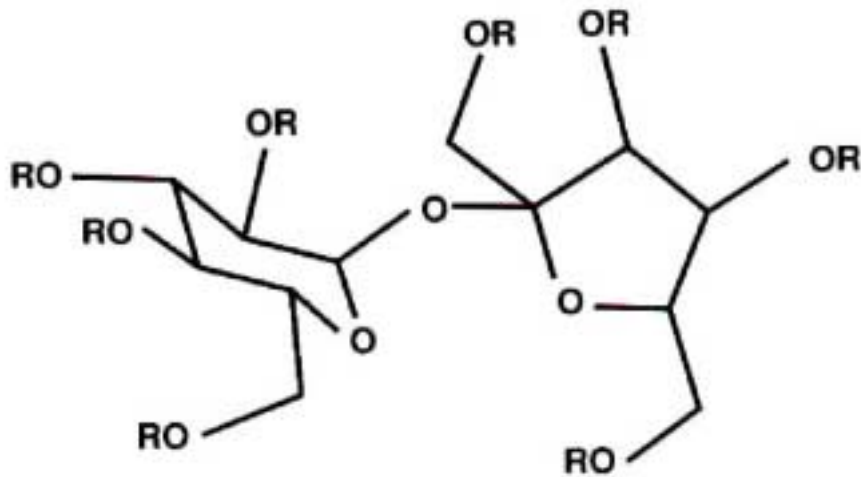
In the meantime, there has been intensive concern with the safety of olestra. Several studies showed that in certain people, olestra caused increased bowel movements and therefore might interfere with the absorption of fat-soluble vitamins and other nutrients. To remedy the problem, foods prepared with olestra are now supplemented with fat-soluble vitamins. As a stipulation of FDA approval, these snacks carry a warning label advising consumers of the potential side effects.



During the past 30 years, Procter & Gamble has invested more than \$500,000,000. on research to modify olestra and to find superior sucrose polyesters (SPEs). They sought to produce non-digestible fat substitutes that could be used interchangeably with natural fats and oils (Glueck *et al.*, 1982; Jandacek, 1991). The petition originally submitted to the FDA in 1976 to use olestra as a means of lowering cholesterol (tentatively withdrawn by Procter & Gamble) was finally approved by Commissioner David Kessler of the FDA on January 24, 1996. However, it stipulated that it was only for use in deep-frying of certain snack foods such as potato chips, tortilla chips, cheese puffs, crackers, and other salty snacks (FDA, 1996; Klis, 1996; Giese, 1996). All products that contain olestra made by Procter & Gamble or other licensed manufacturers are required to have a warning label with the statement, “ This product contains olestra. Olestra may cause abdominal cramping and loose stools in some people.” In spite of this, Procter & Gamble has aggressively marketed its product. It has been on the market for three years and its reevaluation continues for the safety of the public and also in order to address new concerns. These include; what are the long-term effects associated with the consumption of olestra? and, how is this compound degraded in the environment once it passes through the human body?

Commercial olestra consists of a sucrose molecule and a mixture of fatty acid molecules each of which is each made of more than twelve carbon atoms ( $> C_{12}$ ) (Bergholz, 1992a; Miller and Allgood, 1993). Because the structure of olestra bears certain chemical similarities to natural triglycerides (see Figure 2), both molecules have comparable physical and sensory properties (Glueck *et al.*, 1982). Despite chemical

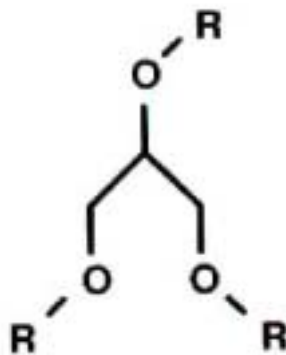
similarities, however, olestra is a much bulkier molecule than most fats and, therefore, not a suitable substrate for lipid-degrading enzymes. As such, it can pass through the human digestive tract without being either hydrolyzed or absorbed by the cells of the enteric wall (Freston *et al.*, 1997).



OLESTRA

(Sucrose with six to eight fatty acids)

R = Fatty acid



TRIGLYCERIDE

(Glycerol with three fatty acids)

R = Fatty acid

Figure 2. Comparison a schematic structure of olestra (top), in this case an olestra octaester, with that of a triglyceride (bottom) (adapted from Bergholz, 1992b) p.142.

## OLESTRA AS A FAT SUBSTITUTE

### 2.1 Definition of olestra

Olestra, also known by its trademark name Olean<sup>TM</sup>, is the generic term used to describe a class of sucrose polyesters which form a chemically heterogeneous group of complex substances made of sucrose and several esterified fatty acids. The name olestra is derived from its molecular structure. The prefix *ol* represents olein and *estr* = *ester* which describes the chemical bond between an acid and an alcohol such as that which binds sucrose to fatty acids. In brief, the term *olestra* represents the chemical combination of fatty acids and a sugar molecule by multiple ester bonds (Procter & Gamble, 1987; in Swanson and Akoh, 1994). Olestra is a heterogeneous mixture of hexa-, hepta-, and octa- fatty acid esters of sucrose. The long-chain fatty acids can be saturated or unsaturated.

### 2.2 Classification of fat substitutes

Depending on the nature of the main molecular constituent, fat substitutes can be divided into three main categories: carbohydrate-based, protein-based, and fat-based.

Carbohydrate-based fat substitutes contain ingredients such as hydrolyzed corn

starch, cellulose gels, or maltodextrins. These can be used to reduce the total fat content of certain food products such as salad dressings, ice cream-type products, and reduced-fat ground beef products. In addition, these products often improve the texture of the finished food because they contribute to thickening or bulking and because they maintain the moisture content. When mixed with gums and water or with emulsifiers, some carbohydrate-based fat substitutes add flavor to a variety of foods and improve the overall quality of the product. A microcrystalline cellulose gel called Avicel is commonly used in the preparation of salad dressings, low-calorie dips, bakery goods, and ice cream products (American Dietetic Association, 1971). In the early 1980s, the National Starch and Chemical Corporation of Bridgewater, New Jersey marketed a product named N-oil that was used with carbohydrate-based ingredients such as tapioca dextrin to replace fats and oils. Carrageenan, a product extracted from seaweed, was introduced into the market by Sanofi Bio-Industrial, Inc. of Waukesha, Wisconsin while oat bran was used to decrease the fat content of ground beef products. Oatrim, a water soluble fiber obtained from oats by the enzymatic hydrolysis of gelatinized milled oat flour, was mixed with extra-lean ground beef to produce “reduced fat” hamburger, bologna, frankfurters and other such products (Artz and Hansen, 1994).

Protein-based fat substitutes introduced into the market in the late 1980s were derived from egg whites, whey, soy, or corn protein. These protein substances were mixed with water in a process called microparticulation in which they were blended, heated, and coagulated. The result was spherical protein particles small enough to allow the particles to roll over one another smoothly, creating a rich texture and creamy taste.

When the resultant particles were mixed with food, they gave the food product a texture similar, or indistinguishable, from that which natural fats impart to the same foods. Simplesse, an example of this type of fat replacement substance, was introduced to the U.S. market in 1988 by the Nutra Sweet Company of Deerfield, Illinois. It is made from skimmed milk and egg white using the microparticulation process and is sold on a commercial scale nationwide. Other fat replacement materials produced by microparticulation are used in the production of a variety of low fat food products including cheese, mayonnaise, frozen dairy desserts, salad dressings, butter, sour cream, and certain baked foods (Krebs-Smith *et.al.*, 1992). DairyLite, a protein-based fat substitute distributed by the John Labatt Ltd., Adult Foods of London, Canada, is made of spherical particles of denatured dairy whey protein coagulate, which can be used as a high protein-low-calorie fat replacer. The size of DairyLite dried particles ranges from 0.1 to 2.0  $\mu\text{m}$  and have volumes ranging from  $3 \times 10^{-2}$  to  $12.6 \mu\text{m}^3$  (Artz and Hansen, 1994). Another soy protein fat replacement material produced from soy protein plays an important role as an additive in meat patties, pepperoni, ground beef, and precooked pizza toppings (Keeton, 1991; in Morrison, 1994). Unfortunately, protein-based fat substitutes, like carbohydrate-based fat substitutes, are not stable at high temperatures and decompose during the cooking process making them essentially useless for anything but cold processed food products.

The third kind of fat-based fat substitutes are stable at high temperatures and can be used for “deep-frying” foods. These are fat replacer products which are synthesized from natural fats and oils and contain a variety of matrix structures (other than glycerol)

to form the inner hydrophilic part of the molecule (Haumann, 1993). The appropriate fatty acids add few calories to the food in which they are incorporated and have been used successfully for some time (Boutte and Swanson, 1994).

A list of fat-based substitutes that are currently under study is shown in Table1.

Table 1. Classification of lipid-based synthetic fat substitutes.

Name	Digestibility	Composition	Company/Inventor
Olestra	Nondigestible	Sucrose polyester, 6-8 fatty acids esterified	Procter & Gamble, Akoh and Swanson
Trehalose, raffinose, sorbitol and stachyose polyester	Nondigestible	Carbohydrate + fatty acids	Akoh and Swanson
Alkyl glycoside polyester	Nondigestible	Alkyl glycoside + fatty acids	Akoh and Swanson
Sucrose ester	Digestible	Sucrose fatty acid ester, 1-4 fatty acids	Mitsubishi-Kasei, Crodesta
Alkyl glycoside ester	Digestible	Alkyl glycoside + fatty acid, mono- and diesters enzymatically synthesized	Mutua and Akoh
Acetylated glucose ester	Digestible	Glucose pentaacetate + fatty acid, enzymatically synthesized	Akoh
Structured lipids	Partially digestible	For example, caprocarylobehenin, (caprenin) etc., structured triacylglycerols	Procter & Gamble, Babayan
EPG*	Partially digestible	Esterified propoxylated glycerol	ARCO Chemical Co.
DDM*	Partially digestible	Dialkyl dihexadecylmalonate	Frito-Lay, Inc.
TATCA*	Partially digestible	Trialkoxytircarballylate	Hamm, CPC Int.
TAC*	Partially digestible	Trialkoxycitrate	Hamm, CPC Int.
TGE*	Partially digestible	Trialkoxyglycerylether	Hamm, CPC Int.
PGE*	Partially digestible	Polyglycerol ester, emulsifier	Babayan
MCT*	Partially digestible	Medium chain triacylglycerol mainly C <sub>8</sub> -C <sub>10</sub>	Babayan
Jobba Oil	Partially digestible	Modified triacylglycerol	Nestec, Ltd.

\* These designations reflect the chemical composition of the synthetic product.

Source: Ref. Akoh, 1995 p. 407.



Methyl glucose polyester (MGPE) which is produced by esterifying methyl glucoside and four fatty acid esters, imitates the chemical structure of natural fats in many ways. It is used as a fat substitute for natural fats and oils such as tallow, milk fat, lard, and vegetable oils in sausage, cheese, ice cream, and many other products.

Dialkyl dihexadecylmalonate (DDM) comprised of a fatty alcohol ester of malonic and alkylmalonic acids is produced by Frito-Lay, Inc. of Dallas, Texas and is expected to be used as lean as is a low-calorie fat substitute in high-temperature frying (Akoh, 1995).

Trialkoxytricarballylate (TATCA) is an ester of tricarballic acid and fatty alcohols manufactured by the Best Foods Division of CPC International of Englewood Cliffs, New Jersey. It can be used to replace such spreadable products as mayonnaise, margarine, and vegetable oil in cooking (LaBarge, 1988; Akoh, 1995).

Sorbitol fatty acid esters, a product of Pfizer Inc. of New York, New York is a low-calorie fat substitute that contains four fatty acid esters on a sorbitol molecule. Pfizer developed sorbitol fatty acid esters for potential application in toppings, frozen desserts, salad dressings, spreads, puddings, shortenings, sauces, meat analogues, baked goods, mayonnaise, gravies, pasta, cooking or frying sprays, and coatings for snack foods. This product is partially digestible and, therefore, far from being the ideal fat substitute (Haumann, 1993).

Caprenin, or caprocarylobehenin, composed of a triglyceride esterified with saturated fatty acids such as capric, caprylic, and behenic, was developed by Procter & Gamble of Cincinnati, Ohio and Grinsted Products, Inc. of Kansas City, Missouri in

1992. Mars, Inc. of Hackettstown, New Jersey and other manufacturers of candy products use caprenin which is only partially absorbed by the human alimentary canal and contributes only five calories per gram of candy, as a substitute for cocoa butter.

Olestra belongs in this group of fat substitutes (Dziezak, 1989). It can be used interchangeably with fat in a wide variety of foods, including ice cream, margarine, cheese, processed meat, and in baked and fried foods. Its stability, smoke point (*i.e.*, thermal decomposition), and flash point are comparable to those of natural fats. Olestra can be blended with vegetable oils (Kester, 1993) and used as such since it can be cooked in the same manner as natural oils. When used to replace fat in foods or used as a cooking medium, olestra has physical and sensory properties similar to those of natural fat. It differs however, in that each gram of olestra, which replaces one gram of natural fat in food eliminates 9 kcal of energy value from that finished food (National Institutes of Health, 1981).

### 2.3 Synthesis of olestra

Carbohydrate fatty acid polyesters like olestra have a moderate to high degree of substitution (DS), (DS = the degree of substitution indicates the number of hydroxyl groups replaced by ester groups in the compound). These compounds are lipophilic, nondigestible and nonabsorbable molecules with physical and chemical properties similar to those of natural fats and oils. Research on low calorie foods is focused on the possibility of extending the use of carbohydrate polyesters such as olestra. The search

for inexpensive, high yield and high volume synthesis processes is intense and highly competitive.

Early synthesis of carbohydrate fatty acid polyesters was focused on sucrose polyesters but a great deal of work now is directed to the synthesis of carbohydrate-based polyesters such as monosaccharide polyesters, disaccharide polyesters (other than sucrose), trisaccharide polyesters such as raffinose polyester, starch polyesters, and alkyl glycoside polyesters.

The synthesis of carbohydrate polyesters was initially investigated by several research groups including Mattson *et al.* (1971), Rizzi and Taylor (1978), Feuge *et al.* (1970), Rizzi and Taylor (1976), and Jandacek and Webb (1978). The primary interests of this research were centered on using various vegetable oils such as cottonseed oil, soybean oil, palm oil, coconut oil, and corn oil as sources of fatty acids. Carbohydrate fatty acid polyesters with a DS > 4 can be prepared by the solvent-free method of interesterification (simple ester- ester interchange reactions) described by Feuge *et al.* (1970). This process depends on mixing molten sucrose and long chain fatty acid methyl esters at temperatures between 170-187°C in the presence of soaps of lithium, sodium, or potassium as catalysts. A limiting factor in this reaction is that sucrose caramelizes at 185°C. The operator, then, is faced with a reaction sequence in which one of the reactants decomposes as the rate of the reaction approaches its maximal value. This is a severe limitation for an industrial scale process. Another major problem with intersterification is that toxic solvents such as dimethylacetamide, dimethylformamide, or dimethylsulfoxide are required to form a homogenous melt that will promote high yields

of product (Mattson *et al.*, 1971; Feuge *et al.*, 1970; Bobalek, 1977; Weiss *et al.*, 1971, 1972). So far these problems have proven insurmountable making the interesterification reaction of very limited value in the food industry.

Carbohydrate polyesters of sucrose with four to eight attached fatty acids (DS 4-8) can be prepared with highly reactive acylating agents such as acid chlorides, anhydrides, or aryl esters (Rizzi and Taylor, 1978). As the degree of substitution increases beyond DS 3 in these products, the rate of lipolysis by intestinal lipases decreases. Two research groups, Akoh and Swanson (1987, 1991) and Mattson and Nolen (1972) showed that as the degree of substitution increased, steric hindrance resulting from the substituted fatty acids increased and apparently reduced the activity of lipolytic enzymes.

Mattson *et al.* (1971) synthesized sorbitol hexaoleate by heating one part sorbitol with five parts of ethyl oleate in dimethylacetamide using sodium methoxide as a catalyst. Reaction times of approximately five hours and a temperature of 180°C gave the best yields.

On the other hand, investigations on the enzymatic synthesis of sorbitol polyesters were not successful. Seino *et al.* (1984) succeeded in obtaining the synthesis of sorbitol fatty acid esters of DS < 4 but these compounds were digestible and therefore, not useful as zero calorie fat substitutes (Seino *et al.*, 1984; in Akoh, 1994a, 1995). Sorbitol esters with DS < 4 are now used as emulsifiers in the food industry. Akoh (1995) reported that the enzymatic synthesis of carbohydrate polyesters of DS > 4 was extremely difficult due to steric hindrance and, consequently, these have not been used commercially.

Rizzi and Taylor (1976, 1978) described a solvent-free, two-stage reaction sequence for synthesizing carbohydrate polyesters that did not employ toxic solvents. In the first stage, a 3:1 mole ratio of fatty acid methyl ester to free sucrose was allowed to react in the presence of potassium soap for two to three and a half hours in order to form a homogenous melt. At this stage, the product contained mainly esters of sucrose with small amounts of DS 1-3 esters. In the second stage, excess fatty acid methyl esters and more potassium hydride were added and allowed to react for an additional 6 hours at temperatures of 130-150°C to produce sucrose polyesters of DS 7-8 with product yields of 90%. In both stages, the sucrate ion generated with alkali metal hydrides (Rizzi and Taylor, 1978) or a Na-K alloy was believed to help catalyze the reaction that yielded sucrose esters (Figure 3). This process has two disadvantages: 1) the two-stage reaction requires prolonged reaction times of as much as 8 to 9 hours; 2) it requires an uneconomical mole ratio of fatty acid methyl esters to sucrose of 16:1. The olestra synthesized by the method of Rizzi and Taylor consists of 99.7% octa- and hepta-esters and 0.3% hexa- or lower esters. The relative composition of the fatty acids making up the ester groups is 19% palmitic, 4% stearic, 33% oleic, 34% linoleic, 9% behenic and 1% others. The method of Rizzi and Taylor (1978) was modified by Hamm (1984). He added methyl oleate and sodium hydrides at the beginning of the reaction and later added sucrose in small increments. With this method, Hamm (1984) obtained sucrose fatty acid polyesters at a theoretical yield of 100% but the DS of the product was 4-8.

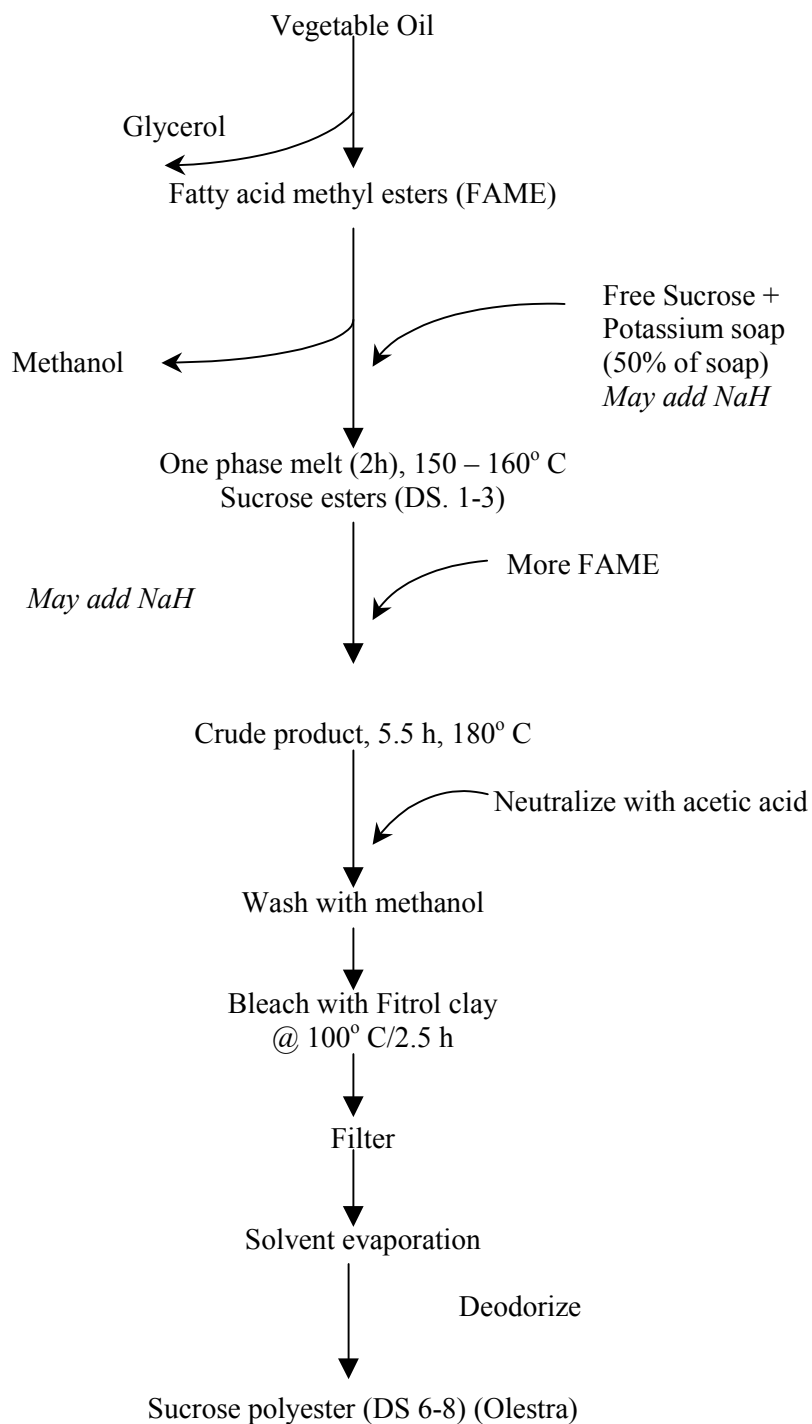


Figure 3. Schematic diagram of the process used for the synthesis of olestra by Procter & Gamble (Akoh, 1994a, 1995) p. 24.

Mieth *et al.* (1983; in Akoh, 1994a) reported 80-90% yields of sucrose polyester by reacting sucrose octaacetate and methyl palmitate in the presence of 2% sodium or potassium metal catalyst at reaction temperatures of 110-130°C for a reaction time of 3 to 6 hours at a pressure of 15-25 mm of mercury. In this process, a clear melt of sucrose octaacetate and palmitic methyl ester was formed before addition of the catalyst. The yields were calculated relative to the starting quantity of sucrose octaacetate. The yield of pure sucrose octapalmitate did not increase significantly by increasing the molar ratio of fatty acid methyl esters to sucrose octaacetate to a level of 10:1.

Volpenhein (1985) improved the original solvent-free process by heating a mixture of carbohydrate, fatty acid methyl esters, 2-methoxy ethyl or benzyl ester, alkali metal fatty acid soap and potassium carbonate or barium carbonate as the catalyst to form a homogenous melt. Excess acyl donor was then added to the melt to yield carbohydrate-fatty acid polyesters at temperatures from 110 to 180°C and pressures between 0.1 and 760 mm of mercury. The optimal catalyst was potassium carbonate and the reaction time for the second step in this process was between 2 and 8 hours. The molar ratio of fatty acid methyl esters to free sucrose was 12:1. The product formed was a mixture of the higher degree of substitution polyesters with yields of 36 to 85% octaester.

Yamamoto and Kinami (1986) used a mixture of sucrose oleate (DS 1.5), molten sucrose, methyl oleate, and a catalyst such as sodium and potassium carbonate to form a homogenous melt at 120-180°C at a pressure of < 10 mm of mercury. The time required for completion of the reaction varied with the reaction conditions but was generally between 1 and 3 hours. Both Volpenhein's (1985) and Yamamoto and Kinami's (1986)

methods required molecular distillation at 60-150°C to remove unreacted fatty acid methyl esters.

Recently, Akoh and Swanson (1990) reported an optimized synthesis of sucrose polyesters that gave yields between 99.6 and 99.8% of purified sucrose polyester based on the initial weight of sucrose octaacetate. This is a one-stage solvent-free process involving mixing sucrose octaacetate, 1-2 % sodium metal as catalyst, and the fatty acid methyl esters of vegetable oil. Heat was applied after the reaction mixture was in place to obtain optimal yields (Figure 4). Formation of the first phase melt was achieved 20 to 30 minutes after heat was applied but high yields were obtained only after the temperature reached 105 to 110°C. Optimal synthesis required approximately two hours in a vacuum of 0-5 mm of mercury. Volatile methyl acetate formed as a result of the interesterification was separated from useful product by trapping in a liquid nitrogen trap (-196°C) thereby driving the reaction towards product formation.

The primary advantage of this process and the one reported by Akoh (1994a) is that the acetate groups from sucrose octaacetate that protect sucrose from heat degradation and caramelization are easily removed. This permits higher product yields and easier isolation and recovery of finished product. The preferred molar ratio of fatty acid methyl esters to sucrose octaacetate is 8:1 because this favors a stoichiometric reaction. The optimal synthesizing reaction condition of sucrose polyester (olestra) is further illustrated in Table 2.

The yields reported by Akoh and Swanson (1990) were greater than those reported by previous investigators (Hamm, 1984; Rizzi and Taylor, 1978; Feuge *et al.*,



1970). Washing with methanol and hexane (Figure 3) removed unreacted fatty acid methyl esters and sucrose plus sucrose polyesters of DS 1-3 (Akoh and Swanson, 1987 and 1990; Yamamoto and Kinami, 1986). Increasing the molar ratio of fatty acid methyl esters to sucrose octaacetate to 12:1 did not increase the yield of olestra above 90.4% of the optimal yield. When the mole ratio was decreased to 6:1, the yield of olestra decreased to 87.6%. This suggested that the optimal ratio of fatty acid methyl ester to sucrose octaacetate lay between 6:1 and 12:1. The yield of olestra as octaester increased to 99.8% when the mole ratio of fatty acid methyl esters to sucrose octaacetate was adjusted to a value of 8:1 (Akoh, 1994a, 1995).

In this one-stage, solvent-free, interesterification process of Akoh and Swanson, they mentioned other novel saccharide polyesters (i.e. monosaccharide polyesters, disaccharide polyesters, trisaccharide polyesters) that this process yielded 97.5% of trehalose octaoleate or 96.0% of sorbitol hexaoleate compared to olestra.

In summary, the synthesis of olestra using sucrose octaacetate, in a one-stage, solvent-free process that works best at 105°C and reaction times as brief as two hours (Akoh and Swanson, 1987). As shown in Figures 3 and 4, the preparation of olestra by the Akoh and Swanson process has more advantage in terms of time and economic aspects than that of the Procter & Gamble process (Akoh, 1994a).

Table 2. Optimized reaction conditions for the synthesis of sucrose polyester.

Oil	Molar ratio FAME to SOAC	Reaction time, h	Temperature ( °C)	Catalyst <sup>d</sup> (%)	Yield <sup>b</sup>
Soybean SPE <sup>c</sup>	10:1	2.0	120	1.0	52.0
Soybean SPE	8:1	3.0	120	1.0	96.1
SPE of (90:10 (w/w) blend of) safflower oil FAME and methyl stearate	8:1	2.0	110	2.0	99.6
Sucrose polyoleate	8:1	2.0	110	2.0	99.8
Sucrose polyoleate	12:1	3.0	105	2.5	90.4
Sucrose polyoleate	6:1	2.5	112	3.0	87.6
Sucrose polyoleate	10:1	2.0	110	2.0	94.5

<sup>a</sup> FAME to SOAC- Fatty acid methyl ester to sucrose octaacetate.

<sup>b</sup> Percent yield by weight of pure SPE as octaester based on SOAC;

<sup>c</sup> SPE synthesized by a two-stage process consisting of melting Na and SOAC first and adding FAME later.

<sup>d</sup> Catalyst-percent sodium metal adds into the sucrose polyester (olestra) synthesis process

Source: Ref. Akoh and Swanson, 1990; Akoh, 1994a; p. 17.

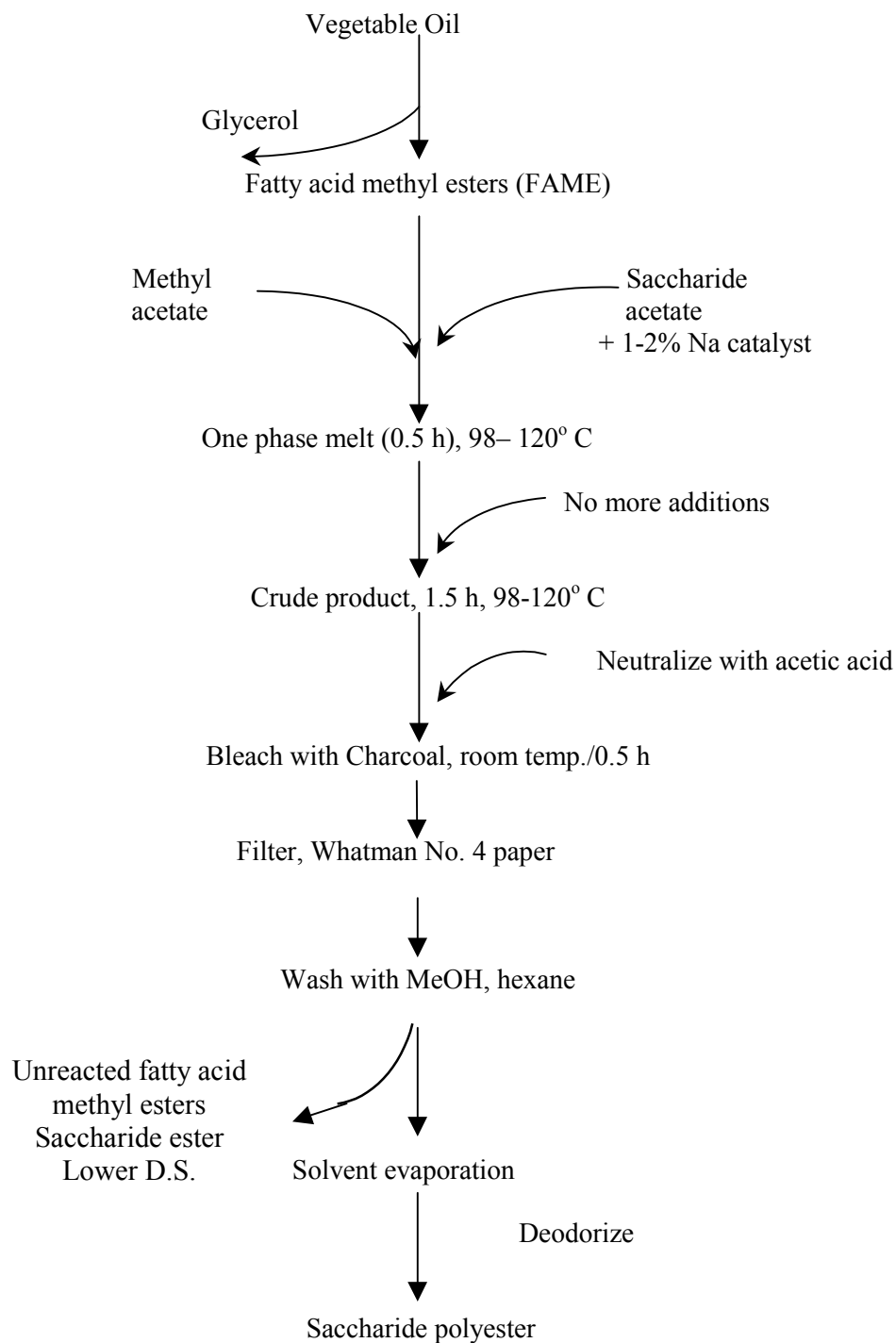


Figure 4. Schematic diagram for the synthesis of saccharide polyester (i.e. sucrose polyester, trehalose polyester, or sorbitol polyester) formation by the process of Akoh and Swanson (Akoh, 1994a, 1995) p. 24.

## 2.4 Physical and chemical properties

Several studies of the physical properties of olestra made with fatty acid side chains of various lengths ( $C_{12}$  to  $C_{24}$ ) were performed and the percentage of concentration of fatty acids in olestra is shown in Table 3. A study by Akoh and Swanson in 1990 showed that olestra had similar appearance and consistency to that of salad oils. Jandacek and Webb (1978) discovered that the pure sucrose octaesters (olestra) had almost identical physical properties to those of natural fats and oils. The results of these comparisons are shown in Table 4. In a discussion of the physical properties of synthetic table oils, including olestra, Hamm (1984) introduced the concept of modifying the degree of unsaturation and chain length of fatty acids to find the most suitable physical properties of such oils for use in various foods.

Table 3. Content of various fatty acids in olestra.

Constituents	% Concentration of fatty acid
<b><i>Major constituents</i></b>	
Total octa-, hepta-, hexaester	$\geq 97\%$
Octa-ester	$\leq 70\%$
Unsaturated fatty acid	25-83%
Saturated fatty acid	$\leq 75\%$
C <sub>16</sub> + C <sub>18</sub> fatty acids	$\geq 78\%$
C <sub>20</sub> and longer fatty acids	$\leq 20\%$
<b><i>Minor constituents</i></b>	
Hexa-ester	$\leq 1.0\%$
Penta- and lower-esters	$\leq 0.5\%$
C <sub>12</sub> + C <sub>14</sub> fatty acids	$\leq 1.0\%$
Free fatty acids	$\leq 0.5\%$

Ref: Allgood *et al.*, 1997, p. 587.

Table 4. Properties of fatty acid octaesters of sucrose ( equivalent triglyceride properties are given in parentheses).

Fatty Acid	Mol. Weight of sucrose ester	Melting Point, °C, $\alpha$ , $\beta'$	Refractive Index, index $n_D^{25}$	Viscosity, centipoise 37°C	Heat of Fusion 37°C	Entropy of fusion Kcal/mol deg $\alpha$ , $\beta'$	Density g/cm <sup>3</sup> , 37°C
Caprylic 8:0	1351.8		1.4608 (1.4482, $n_D^{20}$ ) <sup>a</sup>	240			
Capric 10:0	1576.6	-24.5	1.4625 (1.4447, $n_D^{40}$ ) <sup>b</sup>	269			
Lauric 12:0	1800.6	10.0	1.4638 (1.4479, $n_D^{40}$ ) <sup>b</sup>	287	10.8	0.0689	0.9566 (0.9085, 40°) <sup>b</sup>
Myristic 14:0	2025.4	34.0, 43.0		298	14.5, 16.3	0.0956, 0.104	0.9962 (1.050, $\beta'$ -38°) <sup>c</sup>
Palmitic 16:0	2249.4	50.5, 55.0			16.6, 18.5	0.115, 0.149	0.9919 (1.047, $\beta'$ -38°) <sup>c</sup>
Stearic 18:0	2474.2	61.0, 64.5			17.9, 12.6	0.133, 0.158	0.9840 (1.014, $\beta'$ -38°) <sup>c</sup> (1.043, $\beta'$ -38°)
Oleic 18:1 <i>cis</i>	2458.0		1.4753 1.4674, $n_D^{25}$ (1.4622, $n_D^{40}$ ) <sup>b</sup>	177 (42)			0.9371 (0.9025, 27°) (0.8991, 40°)
Elaidic 18:1 <i>trans</i>	2458.0	7.4	1.4735	234			0.9274 (0.8961, 40°) <sup>b</sup>
Linoleic 18:2 <i>cis</i> , <i>cis</i>	2441.9		1.4875 (1.4712, $n_D^{40}$ ) <sup>b</sup>	94			0.9496 (0.9130, 40°) <sup>b</sup>

<sup>a</sup>Weast, (1972). CRC Handbook of Chemistry and Physics, p. 314.<sup>b</sup>Litchfield, (1972). Analysis of Triglycerides, Academic Press, New York, p. 231.<sup>c</sup>Swern, (1964). Bailey's Industrial Oil and Fat Products, 3<sup>rd</sup> Edition, Interscience, New York, p.100

Source: Ref. Jandacek and Webb, 1978, p. 168.

General properties. Olestra is odorless, has a bland taste, is nonvolatile and has a clear golden yellow to pale yellow color. The nature of olestra is affected by the content of unsaturated fatty acids: that containing small amounts of polyunsaturated fatty acids is light in color and liquid while that containing greater amounts of saturated fatty acids become opaque and solid (Akoh and Swanson, 1990). The liquid form bears a strong resemblance to natural vegetable oils such as safflower and corn oil. On the average, the molecular weight of commercial olestra is approximately 2,400 daltons, the density ranges from 0.88 to 0.91 that of pure water, and the interfacial tension with water resembles that of safflower oil. Olestra is a solid at low temperatures and liquid or semisolid at room temperature. This characteristic depends on the degree of substitution and on the degree of unsaturation of the fatty acids (Swanson and Akoh, 1994). In general, olestra is lipophilic and therefore has a potential to interfere with the absorption of lipophilic components such as fat-soluble vitamins or other nutrients (Jandacek, 1982).

Natural fats, either solid or liquid, are hydrolyzed by enzymes in the intestinal tract and also absorbed by the cells of the intestinal wall. From here they are carried to the body cells by the blood stream. Fats and oils can also be hydrolyzed by bacteria in the intestinal lumen and the released fatty acids will be either used by the bacteria or captured by the cells of the intestinal wall. The released fatty acids are oxidized by the cells of the body with the release of large amounts of energy. Natural fats are broken down by intestinal and bacterial lipases but olestra is a bulkier, more complex molecule compared to natural fats and one probably not available to lipases and other enzymes in the human body or in enteric bacteria. It is postulated that steric hindrances prevent the

formation of enzyme-substrate (ES) complexes with olestra preliminary to hydrolysis. Because it is a bulky molecule which is probably incapable of attaching to cell surface sites, olestra is not absorbed from the gut as are natural fats (Lawson *et al.*, 1997).

As mentioned previously, olestra is different from conventional triglycerides because it is not hydrolyzed or absorbed in the mammalian gastrointestinal tract nor can the bacteria in the human intestine metabolize it (Mattson and Volpenhein, 1972a; Mattson and Nolen, 1972; Jandacek, 1991; Nuck *et al.*, 1994). It appears that it simply passes through the human digestive tract as an inert substance and, consequently, contributes no calories to the diet (Allgood *et al.*, 1997; Lawson *et al.*, 1997).

Hydrophilic-lipophilic balance. Hydrophilic-lipophilic values are used to indicate the solubility or insolubility of surfactants in water. Olestra has a hydrophilic-lipophilic value between 2 and 6. This means that it can be used to create water-in-oil emulsions. The hydrophilic-lipophilic values will vary with the chain length, type, and number of fatty acid molecules attached to the sucrose moiety (Akoh, 1995). This property is useful for the production of emulsifiers in many food products such as margarine, low fat spreads, caramel, candy, shortening, chocolate and butter (Gupta *et al.*, 1983) (Table 5).



Table 5 Hydrophilic-lipophilic balance by water number of sucrose polyesters, and raffinose polyesters compared to lecithin and synthetic surfactants.

Sample	Hydrophilic-lipophilic balance by water no.
Soybean oil SPE <sup>a</sup>	3.0
Soybean oil RPE <sup>b</sup>	4.5
Olestra	3.5
Raffinose polyoleate	6.0
RPE of (80:20 (w/w) blend) safflower FAME <sup>c</sup> and methyl stearate	2.0
SPE of (90:10 (w/w) blend of) safflower FAME and methyl stearate	3.5
Lecithin	4.2
Sorbitan monostearate (span 60)	4.6
Sorbitan monostearate (span 60)	13.0

<sup>a</sup>SPE, sucrose polyester.

<sup>b</sup>RPE, raffinose polyester.

<sup>c</sup>FAME, fatty acid methyl ester.

Source: Ref. Akoh, 1994a, p. 30.

Solubility. Olestra is a non-polar, lipophilic molecule. It is insoluble in water at 5 to 42 mg/L and very soluble in many organic solvents and oils with the octanol:water partition coefficient ( $\log P_c$ ) of 3.55 (Allgood *et al.*, 1997). Akoh and Swanson (1990) reported the solubility of olestra in various solvents such as water, ethanol, soybean oil, safflower oil, hexane, choloform, and glycerin at 25°C and 75°C compared to Ryoto sugar ester (Table 6). The essential parts of this report are shown in Table 6.

Oxidative stability. For both olestra and natural fats, the predominant chemical changes that occur at high temperatures are oxidative reactions involving the fatty acid constituents. The principal byproducts of high temperature degradations, *e.g.*, frying, are the formation of dimers and trimers which are released as radical groups and which then join primarily by bonding at unsaturated bond sites. Both olestra and conventional fats of similar fatty acid composition undergo similar polymerization reactions under the same conditions (Gardner and Sanders, 1990; Henry *et al.*, 1992). When olestra is heated to temperatures as those used in deep frying, its viscosity increases slightly as a result of the formation of polymers (Allgood *et al.*, 1997). These oxidative reactions can be diminished by the addition of antioxidants. For example, the stability of olestra was improved in one study by the addition of 0.02% by weight of a common commercial antioxidant such as tertiary butylhydroquinone (TBHQ) (Akoh, 1994b).

Table 6. Solubility properties of sucrose and raffinose polyesters compared to Ryoto Sugar Esters.

	Solvent and temperature (°C)													
	Water				Soybean		Safflower		Glycerin		Chloroform		Hexane	
	25	75	25	75	Oil	Oil	Oil	Oil	25	75	25	75	25	75
Oil														
Olestra, soybean oils	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
Olestra, soybean oils	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
Olestra	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
Raffinose polyoleate	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
RPE of (80:20 (w/w) blend) safflower fatty acid methyl esters (FAME) and methyl stearate	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
SPE of (90:10 (w/w) blend) safflower fatty acid methyl esters (FAME) and methyl stearate	I	I	I	PS	S	S	S	S	PS	S	S	S	S	S
Ryoto sugar ester 0-1570 <sup>a</sup>	S	S	S	S	I	I	I	I	PS	S	S	S	S	S

<sup>a</sup> Ryoto sugar ester 0-1570; nonionic surfactant/ sucrose fatty acid ester/ food additive, Mitsubishi-Kasei Food Corporation, Tokyo, Japan, (Hydrophilic-lipophilic balance 15) containing approximately 70% monooleate and 30% di-, tri-, polyester

I, insoluble; PS, partially soluble or dispersible; S, soluble.

Source: Ref. Akoh, 1994a, p. 29.

Melting point. Liquid olestra has three different ranges of melting points determined by differential scanning calorimetry (Akoh and Swanson, 1990). The different melting points of olestra are directly related to fatty acid composition (see Table 3) and to the degree of unsaturation of these acids. As shown in Table 4, olestra made predominantly from saturated fatty acids had a higher melting point than that made predominantly from unsaturated fatty acids. Moreover, the chain length of the constituent fatty acids can also affect melting point temperatures. In general, melting points increased with increases in fatty acid chain length.

Polymorphism and heats of fusion. The behavior of olestra is related to its polymorphic form of  $\alpha$ -like and  $\beta'$ -like phases of olestra. The solid phases of pure olestras were determined by infra-red spectra, X-ray diffraction, and differential scanning calorimetry (DSC) techniques. The  $\alpha$ -like phase formed spherulitic crystals which had characteristics (i.e. melting points, diffraction patterns, and infra-red spectra) similar to those of natural fats with similar fatty acid chain lengths. The  $\beta'$ -like phase was the high melting phase of pure olestra (sucrose octaesters) formed by slowly evaporated organic solutions and produced a typical  $\beta'$  phase crystal form like that of natural fats. The typical types of pure olestra (sucrose octaesters) crystal forms after melting and cooling depend on many factors *i.e.* the rate of solidification, molecular composition, and temperature.

The heats of fusion and entropies of fusion were higher for the  $\beta'$ -like phase than those for the  $\alpha$ -like phase and these differences are consistent with the higher degree of crystallinity of the  $\beta$ -like phase, as indicated by its diffraction pattern. The 0.377 nm and

0.420 nm spacings show the  $\beta'$ -like phase to be more ordered than the  $\alpha$ -like phase.

Although the differential scanning calorimetric (DSC) measurements did not indicate contamination of the  $\beta'$ -like phase with  $\alpha$ -like phase, the variability of  $\alpha$ -like melting point described above prevented the confirmation of a pure  $\beta'$ -like phase. Thus the heats of fusion from the  $\beta'$ -like phase may be those from a mixture of the two phases and may correspond to values that are less than those of a pure  $\beta'$ -like phase (Jandacek and Webb, 1978).

Refractive index, viscosity, and specific gravity. Refractive index, viscosity, and specific gravity values used to establish the identity and purity of various sucrose polyesters were provided by Akoh and Swanson (1990) (Table 7).

The refractive index increased directly with the degree of unsaturation. Furthermore, the specific gravity, density, and refractive index of olestra were slightly greater than the specific gravity, density, and refractive index of commercial salad oils such as safflower oils and corn oil (Jandacek and Webb, 1978).

The viscosity of olestra increased with increasing degree of substitution of fatty acids per molecule of sucrose (Akoh and Swanson, 1990). Furthermore, viscosity increased with increasing fatty acid chain length and with the degree of unsaturation (Akoh and Swanson, 1990; Jandacek and Webb, 1978). Consequently, some forms of olestra have viscosity values greater than those of some natural oils. The viscosity of olestra made with soybean oil fatty acids was approximately twice as great that of many natural oils. The viscosity of olestra with a DS of 4 to 8 was similar to that of various vegetable oils (Hamm, 1984).

Table 7. Some properties of liquid sucrose and raffinose polyesters as well as those of some salad oils.

Test Oil	Refractive index(at 40°C)	Specific gravity (at 20°/20°C)	Density, g/cm <sup>3</sup> (at 20°/20°C)	Viscosity at 20°C (cp)	Color	Theoretical mol. wt
Soybean SPE	1.4688	0.9338	0.9321	241	Pale yellow	2310.1 <sup>a</sup>
Soybean RPE	1.4772	0.9367	0.9351	340	Golden yellow	3210.1 <sup>a</sup>
Sucrose polyoleate	1.4669	0.9152	0.9136	235	Golden yellow	2458.0
Raffinose polyoleate	1.4669	0.9048	0.9032	320	Golden yellow	3413.2
RPE of (80:20 (w/w) blend of)						
Safflower FAME and methyl stearate	1.4567	0.8931	0.8915	116	Pale yellow	3431.2 <sup>a</sup>
SPE of (90:10 (w/w) blend of )safflower FAME and methyl stearate	1.4668	0.9046	0.9010	133	Pale yellow	2541.2 <sup>a</sup>
Corn oil	1.4671	0.9184	0.9167	ND <sup>b</sup>	Golden yellow	-
Safflower oil	1.4674	0.9228	0.9212	142	Pale yellow	-

<sup>a</sup>Average molecular weight based on fatty acid composition as determined by gas-liquid chromatography.

<sup>b</sup>ND, not determined.

Ref. Akoh, 1994a, p. 28.

## UTILIZATION OF OLESTRA

### 3.1 Commercial use of olestra

Fat is an essential constituent of all the food consumed by human beings. As such it carries fat-soluble substances that add flavor and aroma to the food and contributes to the texture and pliability of almost all food substances. It also aids in retaining moisture in meats, bakery, and dairy products. It favorably affects the appearance of meats, aids the palatability of almost all foods, and provides lubrication that aids in chewing and swallowing of foods in general. In the preparation of foods, fats and oils heat uniformly and rapidly, do not readily evaporate as does water, and thereby provide the high temperatures required for dehydrating and crisping of certain foods (Calorie Control Council, 1991; in Swanson and Akoh, 1994). Due to its high calorie content, fat serves as a source of energy with the consequence that excessive consumption causes obesity and the disorders associated with it. Obesity is often the source of such disorders as high blood cholesterol, increased risk of coronary heart disease, gallbladder disease and cancer among others (Merten, 1970; Bracco *et al.*, 1987).

Because it has many properties that are similar to those of natural fats and oils, olestra can be used interchangeably with these in the preparation of certain food products

(Glueck *et al.*, 1982; Jandacek, 1991). Many foods made with olestra have the same texture and aroma as those made with animal or vegetal fats. In addition, because it was designed to not degrade or be absorbed by the human intestinal tract tissues, foods made with olestra yield fewer calories than do foods made with natural fats (Table 8).



Table 8. The fat and calorie content for one ounce of potato or tortilla chips fried in oil or olestra under the same conditions.

Product	Fat (g)	Calories
Regular potato chips	10	150
Potato chips made with olestra	0	70
Regular tortilla chips	7	140
Tortilla chips made with olestra	1	90

Source: Ref. USDA Handbook No.8 and Procter & Gamble; Giese, 1996, p. 131.

### 3.2 Clinical trials for the commercial use of olestra

Compared to carbohydrate or protein based fat substitutes which are adversely affected by high temperatures, olestra can be used to prepare foods at high temperatures. No toxic break down products or genotoxic chemicals were found in studies using rats. Fischer 344 rats fed with olestra that had been heated to commercial “deep frying” temperatures (177-185°C) in quantities comparable to those consumed by human (William *et al.*, 1996) showed no noticeable adverse effects. In another study, Fischer 344 rats fed olestra labeled with  $^{14}\text{C}$  sucrose showed no radioactivity in the urine suggesting that neither olestra nor sucrose products were absorbed from the intestinal tract. The same results were obtained using  $^{14}\text{C}$  labeled olestra that was heated to deep fry temperatures (Miller *et al.*, 1995). Olestra that was heated to a temperature of 365°C for 84 hours mixed with vegetable oil blends in different proportions was fed to a large group of rats without ill effect and with no breakdown products appearing in the urine or feces of the test animals (Miller and Long, 1990).

Studies were also conducted to examine the influence of olestra on plasma lipoproteins, and cholesterol metabolism in obese human patients and those with diabetes mellitus. Total plasma cholesterol and LDL cholesterol decreased by 20% and 26%, respectively, in individuals fed olestra in lieu of natural fats. Increased outputs of fecal neutral steroids were observed which suggested a decline in cholesterol absorption in these patients (Grundy *et al.*, 1986).

Although olestra resisted hydrolysis and absorption in the intestinal tract of human beings, it does affect the absorption of other dietary components. Rats fed olestra showed a decline in cholesterol absorption suggesting that the presence of olestra in the intestinal lumen interfered with cholesterol absorption. Both the olestra and cholesterol were excreted in the feces of the test animals (Mattson *et al.*, 1976) in approximately the same amounts as those in which they had been added to the diet. A short term study of olestra as a potential dietary agent for lowering plasma cholesterol was performed using hypercholesterolemic human beings, rats, and dogs. The results were inconclusive and failed to show that the consumption of olestra resulted in reduced, low-density cholesterol assimilation in the test subjects (Fallat *et al.*, 1976a). On the other hand, it was established that olestra affects the absorption of fat soluble vitamins when both were ingested at the same time. The absorption of added vitamin A (retinol,  $\beta$ -carotene), vitamin D (ergocalciferol), vitamin E ( $\alpha$ -tocopherol), and vitamin K (phyloquinone) was severely inhibited when test animals were given moderate doses of olestra instead of natural fats or oils.

To the contrary, several investigations demonstrated that olestra did not affect absorption and utilization of macronutrients or water-soluble micronutrients (Peters *et al.*, 1997). Studies using laboratory animals indicated that olestra had no effect on the growth and health status of animals fed olestra in place of natural fats. The results were the same for water soluble micronutrients and for a variety of macronutrients. In weanling pigs, olestra did not affect digestion, the assimilation of water-soluble micronutrients such as vitamin K or the overall health and growth of the pigs (Cooper *et*

*al.*, 1997a). From these data, it seems clear that olestra did not interfere with vitamin K absorption or the utilization of macronutrients such as carbohydrates, proteins or other water-soluble substances.

In other investigations, it was learned that olestra did not affect blood clotting or prothrombin time in test animals (Cooper *et al.*, 1997b). Double blind, placebo-controlled, clinical trials with ninety healthy adult human beings revealed that olestra had no adverse effects on the overall health picture of the subjects (Koonsvitsky *et al.*, 1997). Further studies showed that olestra had no effect on prothrombin concentrations, prothrombin time, and the absorption of vitamin B-12, nor on the blood concentrations of vitamin D, folic acid, and the micronutrient zinc (Schlagheck *et al.*, 1997a).

Current clinical trials and experiments using humans and various other animals strongly indicate that olestra is nontoxic and has no ill effects on the overall health status of test animals including human beings when used as a fat substitute. Studies conducted with several species of laboratory animals including rats (Miller *et al.*, 1992, 1995; Miller and Long, 1990), guinea pigs (Daher *et al.*, 1992), mini-pigs (Daher *et al.*, 1996), rabbits (Denine and Schroeder, 1993), mice (Lafronconi *et al.*, 1994), hamsters (Skare *et al.*, 1990) and dogs (Miller *et al.*, 1991) showed that olestra was not toxic and that it was neither carcinogenic nor teratogenic.

The possibility of chronic toxicity or carcinogenicity of olestra was investigated using Swiss C D-1 mice in a long-term feeding study. Mice were fed food in which up to 10% of the fat was replaced with olestra for a period of two years. The results of this study which included survival times, time to tumor formation, incidence of tumor

formation, clinical chemistry, ophthalmology, and hematology were reported in 1994. All animals were autopsied and organ weight, tissue morphology and histopathology were also studied in detail. The data clearly indicated that olestra had no effect on these mice when they were compared to control cohorts (Lafranconi *et al.*, 1994).

The effects of olestra on reproduction and offspring development were studied using Sprague-Dawley rats fed different dietary levels of olestra for prolonged periods of time. No adverse effects were observed with mating frequency or mating response, rate of conception, maintenance of pregnancy, embryonic development, and lactation (Nolen *et al.*, 1987). From these data, it was inferred that olestra would probably have no affect on the reproductive physiology of human beings.

It was also shown that olestra enhanced the excretion of some toxic substances from the body. Olestra was used as a scavenger for radioactively labeled,  $^{14}\text{C}$  dichlorodiphenyl-trichloroethane 5 (DDT5). The excretion rates of  $^{14}\text{C}$  dichlorodiphenyl-trichloroethane (DDT) were measured in Mongolian gerbils fed olestra and compared with control cohorts fed only natural fats. Excretion of  $^{14}\text{C}$  dichlorodiphenyl-dichloroethylene (DDE) was two to three times higher in gerbils fed a diet in which 10% of the total fat was olestra (Mutter *et al.*, 1988). In addition, elimination of organochlorines and other toxic chemicals commonly used in the home and in the food preparation industry was enhanced by replacing natural fats in the diet with olestra. Fecal excretion of  $^{14}\text{C}$  hexachlorobenzene was accelerated by feeding olestra, paraffin, and squalene to rats (Richter *et al.*, 1982).

All these studies support the contention that olestra can be used safely as a fat substitute in the diets of animals and human beings. Further, Procter & Gamble suggested that the use of olestra would lead to weight reduction and weight maintenance with consequent decreases in disease processes associated with obesity.

### 3.3 Uses of olestra as an approved food additive

The Food and Drug Administration examined data from many studies on the use of olestra and approved its use in snack foods as requested by Procter & Gamble on January 25 of 1996 (United States Department of Food and Drug Administration, 1996). The FDA also agreed with the contention that olestra showed no evidence of being toxic, carcinogenic or teratogenic and that it had no adverse effects on growth or reproduction (Giese, 1996). However, the FDA did not approve the use of olestra for any food product other than snack foods.

Recent studies and market trials by Procter & Gamble showed that the public at large accepted the taste of olestra in a variety of foods. Clinical trials performed by Procter & Gamble showed that olestra was safe for human consumption when it was used as a food additive in a variety of foods. Research to support their request for the increased use of olestra, including replacement of natural fats and oils in many food items led Procter & Gamble to contend that if it was permitted to replace animal and vegetal fats or oils with olestra, it would have a large ready-made market composed of individuals who wished to reduce their caloric intake. This contention carries the *caveat*

that foods in which natural fats have been replaced by olestra must be amended with 170 IU of vitamin A, 12 IU of vitamin D, 2.8 IU of vitamin E and 8 micrograms of vitamin K, each per gram of olestra.

A new section (172.867) was added to 21 CFR Part 172 in the Federal Register of January 30, 1996 which stated that olestra may be used in “place of fats and oils in pre-packaged ready-to-eat, savory (i.e., salty, or piquant but not sweet) snacks. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients and in flavors (Giese, 1996). The FDA requires specific labeling indicating the quantity of olestra added to the food item.

## ENVIRONMENTAL CONCERNS

### 4.1. Non-hydrolyzed olestra

Fat absorption involves two distinct processes. First the fat molecule is “dissolved” in the cell membrane at a specific site characterized by a chemical complementarity with the target molecule. The fat is “held” by the cell membrane or transported into the inside of the cell. This is followed by a hydrolytic or saponification reaction that cleaves the fatty acids from the alcohol part of the sugar moiety. Various fatty acids and glycerol are the end products of hydrolysis of natural fats and oils. In case of cells producing exoenzymes, the hydrolysis takes place outside of the cell, and the free fatty acids then enter the cells by reacting directly with the cell membrane and then being transported into the interior of the cell. Hydrolysis of fats in the human body is brought about by enzymes produced in the pancreas. These are collectively called lipases and their substrates are the water insoluble esters of primary alcohols (Hofmann, 1976).

Studies involving the hydrolysis process were conducted using olestra and other sucrose polyesters with one to eight fatty acids per molecule (Jandacek, 1991). The results of these studies indicated that mono-, di, and tri-fatty acid esters (DS 1-3) of sucrose were rapidly digested whereas tetra-to octa-fatty acid esters (DS 4-8) of sucrose were more slowly digested or not digested at all. Therefore, Mattson and his colleagues (1972, 1972a) concluded that the higher the number of ester groups per molecule, the



lower the rate of lipolysis. Following their discovery, Mattson and his colleagues created compounds with a high degree of substitution and eventually olestra.

Previously compiled data showed that sucrose octaoleate, closely related to olestra, was not hydrolyzed by mammalian pancreatic lipase (glycerol ester hydrolase, EC 3.1.1.3) (Mattson and Volpenhein, 1972b; Fallat *et al.*, 1976a). Further studies showed that olestra was not degraded in cultures of intestinal or colon bacteria known to produce lipases capable of hydrolyzing natural fats (Nuck and Federle, 1990). The two studies clearly indicated that olestra could pass through the intestinal tract of human beings without undergoing hydrolysis. They also showed that olestra was a non-absorbable substance that would be excreted in the fecal matter in its native condition. In this regard, olestra is similar to common mineral oil which is only sparingly absorbed (Jandacek, 1982) by the human intestinal tract. These unique properties of olestra serve to distinguish it from other synthetic fat substitutes and also from natural fats and oils. As a consequence, olestra does not contribute to the number of calories yielded by the food in which it is included. In reality, olestra increases the caloric value of foods in which it is included as it contains much more energy than do the natural fats it replaces. The molecule of olestra carries six to eight molecules of fatty acids whereas the molecule of natural fat or oil contains only three. Albeit, the energy in the molecule of olestra is not available to the cells of the body and it is excreted with its energy content intact.

Olestra is a much larger molecule than that of natural fats and consequently does not enter the mixed micellar phase in the lining of the small intestine. The molecule is larger and more bulky than the interior of typical micelles (Bernhardt, 1988) making it

totally (Bergholz, 1991) unavailable to the cells of the intestinal lining. This finding was confirmed by a study in which the quantity of undigested olestra was measured in excreted feces using high pressure gel permeation and thin layer chromatography. The quantity of olestra in the feces of test animals was found to be the same as that ingested. These findings were further supported by the data provided by Mattson and Nolen (1972) who showed that the absorption of olestra was inhibited in the small intestine of rats used in their study.

Hager and Schneeman (1986) measured pancreatic enzyme activity and plasma high density lipoprotein (HDL) cholesterol in rats after feeding corn oil, olestra, and hydrogenated palm oil. The results were consistent with previous reports that the group fed high doses of olestra had the lowest level of plasma cholesterol and also the lowest levels of HDL cholesterol when these were compared to the other two groups. In another study, the rate of olestra emptying from the stomach was measured. Normally, fat leaves the stomach more slowly than fluids such as water or milk due to its lower density and greater viscosity but olestra leaves the stomach at approximately the same rate as water (Cortot *et al.*, 1982). The mechanism involved, is not yet understood.

Olestra in the oil phase absorbs both hepatic and dietary cholesterol thereby excluding them from micellar absorption. Unlike conventional fats, olestra persists in the lipid phase mixed with other fats and oils without being metabolized or absorbed while the natural fats and oils are removed from the mixture. Fallat and his collaborators (1976b) showed that more than 97% of ingested olestra was recovered in the stool after it was fed to human beings. Furthermore, results using high pressure gel permeation and

thin layer chromatography demonstrated the fact that olestra was excreted unchanged in the feces (Fallat *et al.*, 1976<sup>b</sup>). These findings were supported by those of Nuck and Federle (1990) who showed that olestra was not degraded by the bacteria of the human colon under anaerobic conditions. In this manner, olestra plays an important role in eliminating lipophilic molecules such as cholesterol (Jandacek, 1984; Mattson *et al.*, 1976), vitamin A (Jandacek, 1984; Mattson *et al.*, 1979), and dichlorodiphenyl trichloroethane (DDT) (Mutter *et al.* 1988; Volpenhein *et al.*, 1980).

The liver is a likely organ to examine for possible accumulation of olestra or its metabolites after long-term studies where olestra was administered by either feeding or intravenous injection. Examination of the livers of animals fed olestra supported earlier reports that olestra was not absorbed after administration by either of these two routes. These studies also showed that although olestra was taken up by the tissues of the liver and the spleen, it was excreted without undergoing chemical changes (Mattson and Jandacek, 1991). Monkeys fed olestra as 8% and 9% of their diet fat for 24 and 38 months, respectively, yielded no accumulation of this material in the liver or other tissues examined at autopsy (Wood *et al.*, 1991).

Since neither cells of the body nor intestinal microorganisms hydrolyzed olestra, it was assumed that it reached the colon and was excreted in its native state. The result in human beings and other animals was a fecal material with a high content of fat (olestra). This caused an uncomfortable diarrheic condition called steatorrhea in some individuals (Jandacek, 1982, 1984). The addition of olestra to the diets of animals also increased the frequency of defecation (Jandacek, 1982). In addition to this, it was noted that neutral

steroid excretion increased when olestra was added to the diet of most animals tested (Jandacek, 1982).

Concern regarding the fate of olestra in domestic sewage and in the environment is based on the fact that Procter & Gamble scientists state categorically that enteric microorganisms do not hydrolyze olestra. If they are correct, then there is the potential for the accumulation of olestra in the environment.

#### 4.2 Degradation of olestra in the human gut

Because fecal bacteria from the intestinal tracts of human beings failed to metabolize olestra, it was suggested that this compound would probably pass through the aerobic activated sludge sewage treatment process undegraded. If this is correct, it would follow that the olestra in the discharge from the sewage treatment plant would also survive degradation by soil bacteria. The result of this imaginary sequence of events would lead to the accumulation of large quantities of olestra in the environment. The impact of the accumulation of olestra in the environment cannot be evaluated at this time.

The possibility exists, however, that olestra may be degraded by environmental bacteria employing metabolic pathways other than those beginning with the hydrolysis of ester bonds. Nuck and his collaborators (1994) suggested the possibility of enzymatic attack on the alkyl chain of constituent fatty acids. This reaction is known to occur under aerobic conditions and a molecule of oxygen is required for the cleavage of the alkyl chain (Nuck *et al.*, 1994). In the human gut, however, this reaction is unlikely because

the conditions that prevail are reductive and oxidative reactions would probably not take place there. Attacking the alkyl chain at the omega ( $\omega$ ) carbon site requires oxygen and the human colon has little available oxygen. The human intestinal tract, including the colon, contains nitrogen (59.4%), methane (29.6%), carbon dioxide (10.3%), and traces of hydrogen sulfide and hydrogen. The oxygen content is of the order of 0.7% of the total gas volume when it is present. (Orten and Neuhaus, 1982a, 1982b).

#### 4.3 Degradation of olestra under anaerobic conditions by fecal flora

Several of the studies cited above demonstrated that olestra was not hydrolyzed in the intestine of either rats or human beings (Mattson and Nolen, 1972; Fallat *et al.*, 1976a; Jandacek, 1982, 1984). Nuck and his colleagues (1994) evaluated the role of the colon bacteria in the degradation of olestra *in vitro*. They postulated that intestinal microorganisms would degrade olestra and yield long chain fatty acids, volatile fatty acids, carbon dioxide and methane as the degradation products. Enteric bacteria were isolated from the feces of seven subjects whose diet was supplemented with olestra for varying periods of time up to 31 days. Mixtures of olestra with  $^{14}\text{C}$  labeled fatty acids and natural fats were incubated with the isolated bacteria for 72 hours at  $37^{\circ}\text{C}$  anaerobically under conditions simulating the human colon. No free  $^{14}\text{C}$  fatty acids or  $^{14}\text{C}$  carbon dioxide were detected in the cultures studied. In addition, emulsifiers were added to the flask cultures in efforts to simulate the environment of the colon. The octa- and hepta-esters of sucrose were measured after incubation and were found to be present

in the same amounts in which they were added at the beginning of the experiments. These studies showed that bacteria from the intestinal tracts of all seven human subjects did not cleave the ester bonds of olestra under anaerobic conditions. The fatty acid composition of olestra after incubation had not changed from that at the beginning of the experiment. In this study, maximal sensitivity was made possible by using olestra with radioactively labeled carbon atoms at the most labile positions of the fatty acid molecule.

Results of the *in vitro* study agreed with those from prior *in vivo* studies of mammalian lipases (Mattson and Volpenhein, 1972a) and support the claim that olestra is not metabolized. Many bacteria possess inducible enzyme that require the presence of a specific substrate before they are synthesized by the cell. This can be better seen in the laboratory when the bacteria are deprived of nutrients which they can utilize and must either synthesize an enzyme which allows them to metabolize an alternative substrate or starve. Nuck and his colleagues (1994) studied the adaptation to olestra *in vivo* by feeding cookies containing olestra to seven subjects for up to 31 days. In spite of the prolonged time of exposure which could have allowed bacterial adaptation, no metabolism of olestra was observed *in vitro*. This experimental procedure would allow the enrichment of an existing population of bacteria capable of utilizing olestra as a growth substrate but it would probably not cause the induction of suppressed enzymes. Nonetheless, these data indicated that the intestinal bacteria of humans were unable to metabolize olestra either aerobically or anaerobically. Although it could be argued that neither 72 hours nor 31 days were sufficiently long incubation periods, it is more likely

that bacterial lipases as mammalian lipases, could not hydrolyze olestra, possibly, due to steric incompatibility of enzyme and substrate.

## CONSEQUENCES ARISING FROM THE USE OF OLESTRA

### 5.1 Human reactions

When the FDA initially approved olestra for use as a food additive, the most common reaction was optimism on the part of consumers. As a result, Procter & Gamble aggressively promoted olestra in the marketplace. Furthermore, they emphasized the notion that olestra was safe for human consumption. Market trials, however, soon convinced the public that in some individuals, olestra caused flatulence, loose stools, and some diarrhea. Experience has shown that the number of individuals adversely affected was small and the product slowly made inroads into the market. In spite of the many assurances from Procter & Gamble, many questions and concerns still exist. Some of these are:

- 1 Is it true that olestra provides no calories?
- 2 Does olestra taste as good as ordinary fat?
- 3 Is it safe for human consumption?
- 4 Does olestra have short-term and long-term side effects?

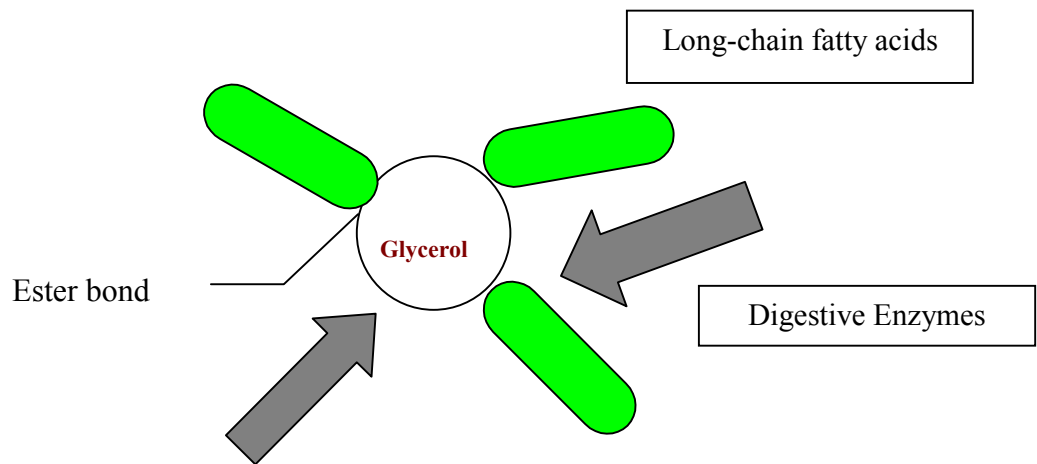
Further research is required to answer these questions.



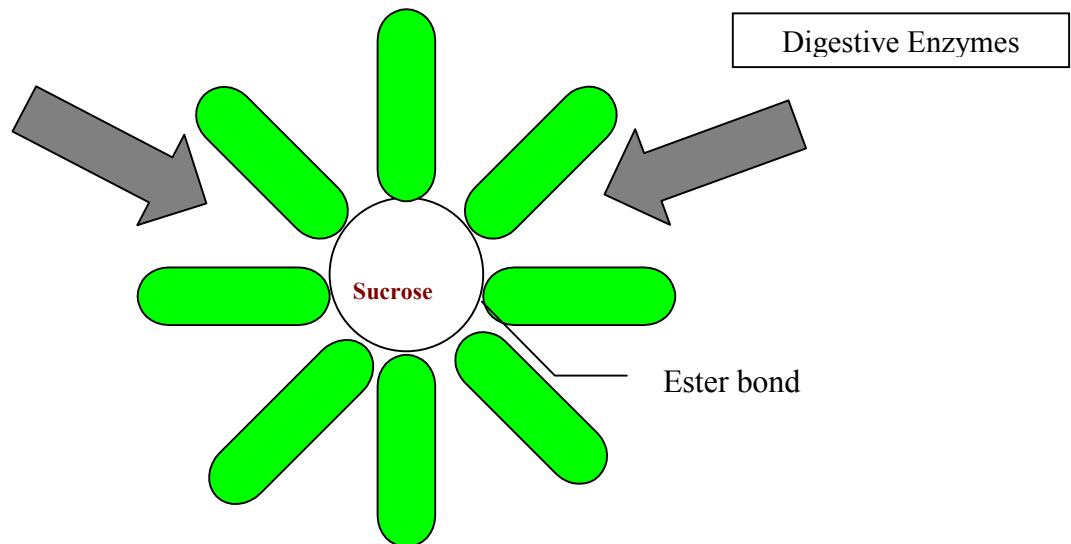
## 5.2 A non-digestible and non-absorbable fat substitute

The potential for olestra to affect gastrointestinal structure and function and the absorption of nutrients from the gut, has been extensively investigated. The nondigestible and nonabsorbable characteristic of olestra is the basis for its effectiveness as a fat substitute as well as the cause of its side effects. Natural triglycerides are hydrolyzed by pancreatic lipase and transported in amphipathic micelles and intracellular carrier molecules across the intestinal epithelium into the lymphatic system (Lawson *et al.*, 1997) although native triglyceride absorption is minimal. Olestra is not absorbed in the gut because it does not undergo hydrolysis. Its bulky structure probably causes steric hindrance so that it is not attacked by human or animal digestive enzymes (Peters *et al.*, 1997) (see Figure 5 and 6). This view is supported by the observations of Mattson and his colleague (1972a) using rat pancreatic extracts. They showed that though olestra, which has 6-8 fatty acid esters is not hydrolysed, olestra with less than four fatty acid esters undergoes complete hydrolysis and those with 4-5 ester groups undergo slow but detectable hydrolysis. Because there is no digestion, it is inferred in this case that absorption is minimal. The lack of absorption is further confirmed by another 1972 study in which the thoracic ducts of rats were cannulated allowing the lymph to be collected and measured for orally fed  $^{14}\text{C}$ -labeled olestra (Mattson and Nolen, 1972). The amount of  $^{14}\text{C}$  radiolabel collected was less than 2% of the dose given orally to the rats, thus demonstrating that these olestras were essentially not absorbed.

In addition to studies with laboratory animals, investigators also conducted short-term studies on the absorption of olestra by human beings. After normalizing diets for 20 days, 5 human subjects received 50 grams of olestra per day for 10 days. Based on measurement of dietary fat intake and excreted fecal fat, absorption of olestra was calculated at about 2.3%, which was considered essentially nil (Fallat *et al.*, 1976b). The most definitive assessment of this property, however, came from a series of absorption, digestion, metabolism, and excretion studies. In one such study, a uniformly  $^{14}\text{C}$ -labeled olestra sample was given to 344 Fischer rats in its pure form and in a form resembling that found in savory snacks by deep-frying the sample (Miller *et al.*, 1995). Urine, expired  $\text{CO}_2$ , and feces were collected continuously for 7 days and the radioactivity measured. More than 99.83% of the radioactivity was not absorbed and was found in the feces or found unaltered in the lumen of the intact gastrointestinal tract. Overall, the fraction of olestra absorbed was found to be between  $7 \times 10^{-5}$  and  $1 \times 10^{-3}$  % of the total oral dose, which, again, was essentially nil.



**Natural fat:** Lipases hydrolyze the ester bonds liberating fatty acids before absorption by the cell.



**Olestra:** Digestive enzymes are unable to reach the ester bonds due to steric hindrance. As a result, olestra does not release fatty acids.

Figure 5. Effect of digestive enzymes on natural fat and on olestra (adapted from Fackelmann, 1996) p. 61.

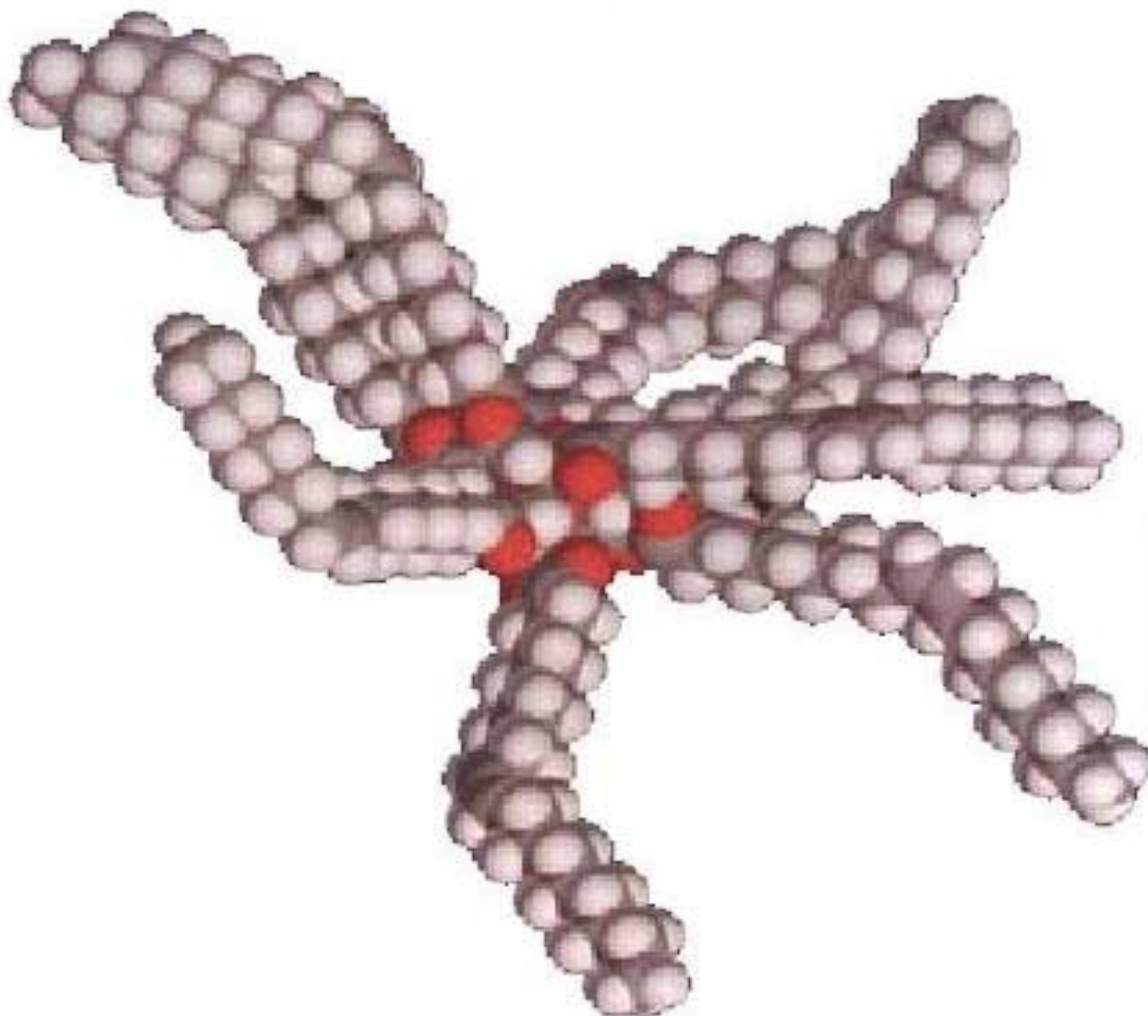


Figure 6. The space-filling model of sucrose octaoleate (olestra) (adapted from Haumann, 1993) p.1226.

### 5.3 Depletion of fat-soluble vitamins

Lipophilic nutrients such as natural fat, fat-soluble vitamins or fat-soluble oral medications require dietary fat and bile for successful absorption into the blood. These compounds are incorporated into the amphipathic micelles and transported to the intestinal villi where they are absorbed (Lawson *et al.*, 1997). Because olestra is lipophilic and nonabsorbable, it is likely that certain lipophilic compounds taken with olestra may be dissolved by olestra during their gastrointestinal transit and may become unavailable to intestinal micelles (Hunt *et al.*, 1998). Three factors play important roles in determining this likelihood. First and most importantly, the hydrophobic (lipophilic) quality of the compound will determine how much affinity that compound has for olestra or lipid in general. This can be measured by calculating the octanol-water partition coefficient ( $P_c$ ) of the molecule in question. A high  $P_c$  value indicates the greater affinity of a molecule for the octanol phase and thus indicates that it is more lipophilic. Table 9 illustrates the relationship between the lipophilicity of a given compound and the potential of olestra to interfere with absorption (Lawson *et al.*, 1997). A second critical factor is the timing of this interaction. A lipophilic substance consumed at the same time as olestra would be most affected because olestra and that substance would be in the gastrointestinal tract simultaneously, thus allowing for the two compounds to interact (Daher *et al.*, 1997). Conversely, the greater the time between the consumption of the compound in question and olestra, the less chance of interaction and therefore the less chance it would affect absorption. Another important element affecting this interaction is

the concentration of olestra in the gastrointestinal tract relative to the lipophilic molecule (Lawson *et al.*, 1997). In general, the greater the concentration of olestra, the greater the chance of absorption.

A number of studies were conducted to assess the effect of olestra on the absorption of specific fat-soluble vitamins. Vitamin A, vitamin D, vitamin E, and vitamin K are soluble in olestra. The absorption of retinol, a derivative of vitamin A, ( $\log P_c = 7.6$ ) was minimal in human trials and significant reduction in absorption only occurred at extremely high level of olestra. A 19% reduction in the absorption of retinol required 32 grams of olestra in a meal (Daher *et al.*, 1994). A dose of olestra of 20 grams had no effect on the absorption of retinol. A study conducted by Procter & Gamble in 1997 concluded that normal daily consumption of olestra would likely not affect some of the dietary components (i.e. retinol and oleic acid) with a  $\log P_c$  value less than 8 (Lawson *et al.*, 1997). It concluded with the assertion that an individual would normally ingest 6.9 grams of olestra per day (Webb *et al.*, 1997) and, consequently, that this would not affect vitamin absorption.  $\beta$ -Carotene, a precursor to vitamin A, has a higher octanol-water partition coefficient ( $\log P_c = 17.6$ ), and was considerably more affected by olestra. Eighteen grams of olestra per day reduced the absorption of  $\beta$ -carotene by 27% (Koonsvitsky *et al.*, 1997). Similarly, in another randomized, double-blind, placebo-controlled study where 12.4 grams per day of olestra were given to 53 subjects, plasma levels of  $\beta$ -carotene were decreased by 34% (Weststrate and Van Het Hof, 1995).

A study was conducted to determine the amounts of vitamins D and E needed to offset the effect of olestra on the availability of these vitamins (Schlagheck *et al.*, 1997b).

The investigators recruited 102 normal healthy males and females who were given varying amounts of olestra plus measured amounts of vitamins D and E for 8 weeks in a parallel, double-blind study. Serum concentrations of  $\alpha$ -tocopherol and 25-hydroxyergocalciferol were successfully restored to control concentrations by vitamin supplementation in a dose-dependent manner. Similarly, Koonsvitsky and his coworkers (1997) conducted a human trial study on the effect of olestra on vitamins A, D, E, K and  $\beta$ -carotene. Subjects in a double-blind, placebo-controlled 16 week study, were started on 18 grams per day of olestra and  $\alpha$ -tocopherol levels were reduced by 6% and  $\beta$ -carotene by 27%. The 25-hydroxyergocalciferol and retinol levels were decreased; however, these decreases were not statistically significant. As an indirect measure of vitamin K, the investigators measured prothrombin time, which is an indication of blood coagulation time and, indirectly, vitamin K level. It was not significantly changed by olestra.

From the data gathered, it is evident that the absorption of fat-soluble nutrients such as vitamins A, D, E, and K, the less lipophilic molecules (with a  $\log P_c$  value less than 8), were not significantly affected by the lower doses of olestra. Certain vitamins such as E and  $\beta$ -carotene were affected more by olestra than vitamins D, K, and retinol. It may be surmised that these results illustrate the principle that olestra being a highly lipophilic molecule tended to interact and thus influence the absorption of such nutrients.

Table 9. Effect of olestra on the absorption of dietary components and drugs measured in acute and long-term human studies<sup>a</sup>.

Substance	Log $P_c$ <sup>b</sup>	Human trials	Olestra (g/day)
β-carotene	17.6	Y	8
α-Tocopherol	12.2	Y	8
Phylloquinone	11.7	Y	8
Ergocalciferol	10.4	Y	8
Retinol	7.6	Y/N	32
Norgesterol	3.5	N	18
Diazepam	2.7	N	18
Folic Acid	-2.0	N	32

Y= absorption was decreased;

N= absorption was unaffected;

<sup>a</sup>This table shows the relation between lipophilicity and effect of olestra on absorption.

<sup>b</sup>Log $P_c$  values are octanol-water partition coefficients which are normally expressed in units of Log<sub>10</sub>. Therefore, a difference of 1  $P_c$  indicates tenfold difference in lipophilicity. Octanol-water partition coefficient ( $P_c$ ) is a mathematical value indicating the lipophilicity of a molecule and it can also be calculated from the molecular structure. This is determined experimentally by determining the relative distribution of the molecule between octanol and water. Lipophilic molecules have  $P_c$  greater than 0; Water soluble substances have  $P_c$  less than 0. For example, folic acid is water soluble and has  $P_c$  value of less than 0. Absorption of substances having  $P_c$  values of up to 3.5 are not affected by olestra. Absorption of substances with  $P_c$  values of 7.5 or above are highly affected. Further, more lipophilic molecules i.e. ergocalciferol were affected by lower dietary doses of olestra (8 grams per day) whereas less lipophilic molecules such as Norgesterol are not affected even at 18 grams of olestra per day.

Ref: Lawson *et al.*, 1997, p. 676.



#### 5.4 Clinical symptoms

Because olestra remains in the gastrointestinal tract, and consequently can dissolve the lipophilic nutrients such as fat-soluble vitamins, cholesterol and bile, it will cause the accumulation of these lipophilic compounds in the gastrointestinal tract (Hunt *et al.*, 1998). Studies of gastrointestinal transit have shown that the consumption of olestra with food does not affect gastric emptying, or short or long bowel transit times. In a study involving 30 healthy human subjects, substitution of up to 30 grams of olestra in a meal with 45-grams of fat did not significantly alter gastric, small bowel, or large bowel transit (Aggarwal *et al.*, 1993). It appears, then, that the presence of olestra in the gastrointestinal tract did not alter gastrointestinal mobility.

In addition, olestra did not affect biliary secretion. In a study involving eight healthy volunteers randomized with respect to olestra consumption, digestible fat, or saline solution in a balanced crossover design, ingestion of olestra, in contrast to digestible fat, did not stimulate gallbladder emptying or release of cholecystokinin (Maas *et al.*, 1997, 1998). Therefore, it appeared that olestra had no effect on bile secretion but if consumed with standard triglycerides it resulted in sequestration of bile within the gastrointestinal tract and therefore, indicated that it may have significant effects on bile acid absorption.

In addition, histological samples obtained after long-term feeding studies showed that olestra did not cause injury to the gastrointestinal mucosa (Thompson *et al.*, 1998). Olestra and triglyceride ingestion resulted in a similar frequency of symptoms in normal

subjects and in people with chronic inflammatory bowel disease in remission (Hunt *et al.*, 1998). Essentially, olestra traversed the digestive tract intact to become a stool additive. Certain subjects developed changes in the frequency of bowel movements and in stool characteristics due to the presence of olestra in the stool.

Numerous studies were conducted to assess the frequency of these side effects. Human studies thus far have yielded equivocal results. In this reviewed thesis, only the most recent and most pertinent clinical trials were examined. In one such study, two three-month, double-blind, placebo-controlled, randomized, cross-over trials of olestra feedings were performed in healthy volunteers (Kelly *et al.*, 1998). Subjects consumed 20 to 40 grams of olestra. The frequency of bowel movements and fecal urgency were increased. Anal leakage occurred in 7.2% of the subjects studied. Abdominal pain was more frequent in subjects receiving olestra and was significantly greater than in the control group after eight weeks of feeding. The ingestion of food containing 20 to 40 grams of olestra daily provoked significant gastrointestinal problems. This intake, however, was greater than that to be expected from the use of olestra in snack foods. In another double-blind study, a total of 1,123 volunteers were randomly given an unlabeled bag of potato chips made with olestra or with natural triglyceride during a free movie screening (Cheskin *et al.*, 1998). Total and specific gastrointestinal symptoms reported during a telephone survey were conducted from 40 hours to 10 days after ingestion. The study showed that consumption of olestra potato chips during one sitting was not associated with increased incidence or severity of gastrointestinal symptoms.

Another study examined recurrence of symptoms in subjects that had previously reported gastrointestinal symptoms which they attributed to consumption of olestra (Zorich *et al.*, 1997a, 1997b). Fifty-seven such subjects received two ounces of potato chips fried in olestra or in triglyceride. Again, these subjects were evaluated by follow-up telephone interviews. The investigators concluded that consumption of potato chips fried in olestra was no more likely to result in reports of gastrointestinal symptoms than consumption of snacks prepared with triglycerides as part of the usual diet, even in individuals who had claimed intolerance to olestra.

## RELATIONSHIP OF MICROORGANISMS TO OLESTRA

### 6.1 Development of olestra microbiology

Microorganisms degrade most natural organic molecules and in turn, derive energy or nutrients from these molecules. The term biodegradation is widely used to describe this process in the environment.

Much research has been reported on the possibility of degrading olestra under anaerobic conditions by the intestinal microflora. Though these studies indicate that olestra is not degraded under anaerobic conditions in the gut, this does not mean that other, non-enteric, microorganisms cannot degrade this compound.

The degradation of olestra, if it occurs, has to start with an attack on the alkyl chain of constituent fatty acids at the omega carbon site in a reaction that requires oxygen. Lee and Ventullo (1996) noted that various aerobic bacteria and fungi found in diverse habitats such as activated sludge, soils, and compost have the ability to utilize olestra as a sole source of carbon and energy. The fungi which degraded olestra included *Trichoderma*, *Cladosporium*, *Monocillium indicum*, and *Verticillium albo-atrum*. They also isolated *Pseudomonas aeruginosa* capable of degrading olestra from activated sludge. This organism degraded both  $^{14}\text{C}$  fatty acid labeled and  $^{14}\text{C}$  sucrose labeled olestra during eight days of incubation. After 69 days of incubation, >98% of  $^{14}\text{C}$  labeled

sucrose and >72% of  $^{14}\text{C}$  labeled fatty acids were mineralized to  $^{14}\text{CO}_2$ . These results suggested that olestra-degrading microorganisms were present in environments previously not exposed to olestra and that olestra could serve as the carbon and energy source for them. They also noted that olestra labeled in the fatty acid moiety was rapidly converted to  $^{14}\text{CO}_2$  without a lag phase while mineralization of the sucrose moiety was preceded by a short lag phase, suggesting that fatty acids were cleaved first by esterases. Thin layer chromatographic analysis of the products also revealed that concurrent with the loss of  $^{14}\text{C}$  labeled sucrose, olestra appeared as a single peak with  $R_f$  value of 0.05. Based on this evidence, Lee and Ventullo (1996) suggested that olestra, i.e., the octa-ester was cleaved and fatty acids were liberated one by one to the hepta-ester, then hexa-ester, etc. As this degradation progresses, the molecule is converted to more polar material such as the penta-ester, tetra-ester, etc. These are subsequently broken down to carbohydrate and residual fatty acids. Thus the initial step in the olestra metabolism by microorganism appears to be cleavage of fatty acid moieties by esterases. Such esterases appear to not be affected by steric hindrance as are the animal esterases in the intestinal tracts of humans, dogs, and rats.

## FATE AND DISTRIBUTION OF OLESTRA IN THE ENVIRONMENT

### 7.1 Contamination of sewage plants with olestra

To determine the potential adverse impacts to the environment, numerous investigations were conducted in which olestra was added to the environment in domestic wastewater, treated or untreated sewage, or in failing septic systems (Allgood *et al.*, 1994). The findings indicate that olestra did enter the environment but that its presence in the soil was not deleterious. To the contrary, others found that olestra improved the environment (Allgood, 1994b; Overcash *et al.*, 1994). One study showed that olestra increased the plastic qualities of the soil and that it also increased the liquid holding capacity of the soils tested (Logan *et al.*, 1996). Another finding noted that olestra was not toxic to fish, or to aquatic organisms such as algae, zooplankton, and bacteria, or to terrestrial organisms such as earthworms (Allgood, 1994a).

There is concern regarding the effect of olestra on sewage treatment plants. Some investigators noted that olestra had no undesirable effects on the functional processes of wastewater treatment plants such as removal of total suspended solids, total organic load, or sludge dewatering (Greff *et al.*, 1995; Logan *et al.*, 1996; McAvoy *et al.*, 1996; Overcash *et al.*, 1994). It was suggested that olestra was removed during the conventional wastewater treatment by sorption to solids and settling in the clarifying

process (McAvoy *et al.*, 1996). In the activated sludge process, the mineralization of radiolabeled olestra was demonstrated using traps to capture radioactive CO<sub>2</sub> (Allgood *et al.*, 1994). The actual biodegradation during wastewater treatment was minimal due to the short residence time (Allgood *et al.*, 1994; McAvoy *et al.*, 1996) in the plant. In the activated sludge process, the biodegradation of olestra was demonstrated by the hydrolysis of radiolabeled olestra, (Allgood *et al.*, 1994; McAvoy *et al.*, 1996).

## 7.2 Contamination of soils with olestra

Olestra removed during wastewater treatment by primary sorption to solids and settling during the clarifying process was deposited in soils treated with activated sludge (McAvoy *et al.*, 1996). The half-life of olestra in soil was measured as 10 and 88 days for liquid and solid olestra, respectively (Allgood *et al.*, 1997, McAvoy *et al.*, 1996). Both liquid and solid forms of <sup>14</sup>C-labeled olestra have been mixed with soils collected from sludge-treated agricultural areas. Soil microorganisms were capable of mineralizing the olestra to CO<sub>2</sub>; however, the solid olestra was more refractory than the liquid form. For example, 50% of the liquid olestra was transformed to <sup>14</sup>CO<sub>2</sub> in 66 days while it took over 386 days to degrade 45% of the solid olestra (McAvoy *et al.*, 1996).

Other reports indicated that both liquid and solid forms of olestra at a concentration of 5,000 mg olestra /kg soil were not toxic to the soil ecosystem. For example, there were no adverse effects on earthworms or microorganisms (Allgood, 1994b). Because at least one-third of the municipal sewage sludge in the USA is

recycled to land for agricultural benefit (Logan *et al.*, 1996), there is much interest on the effects of olestra in soils when olestra is mixed with sludge. Logan and coworkers (1996) evaluated the potential impact of olestra entering the environment. Two different concentrations of liquid and solid forms of olestra were added to sewage sludge in four types of soil. Miamian silt loam (fine, mixed, mesic, Typic Hapludalf), Kokomo silt loam (fine, mixed, mesic, Typic Argiaquoll), Hazleton sand (loamy-skeletal, mixed, mesic, Typic Dystrochrept), and Paulding clay (very fine, illitic, nonacid, mesic, Typic Haplaquept) as components of sewage sludge. The physical properties of the soils were evaluated for particular and bulk densities; water retention; saturated hydraulic conductivity ( $K_s$ ); shrinkage; water-stable aggregates; Atterberg limits; and pocket penetrometer resistance effects (Logan *et al.*, 1996).

Most data indicated that the sludge added was beneficial for soil productivity by increasing the porosity, water retention, hydraulic conductivity, water stable aggregates, and penetrometer resistance. There were only a few cases where olestra added to the sludge gave an effect over and above that of the sludge alone. For example, particle densities and bulk densities of soils were diminished by the addition of sludge and sludge with olestra; and there were no additional effects caused by olestra above those caused by to sludge alone. The sludge increased porosity and the capacity of the soil to transmit air and water to plant roots. On the other hand, there were no effects from olestra on water retention over and above the effects of the sludge; and water retention was increased equally by both treatments.



The studies of Logan and coworkers (1996) on the physical properties of soil demonstrated there were no effects from adding olestra. They also demonstrated that liquid and solid olestra resulted in less soil dispersion than sludge alone. Furthermore, their reports mentioned that olestra increased soil aggregation when compared to sludge alone with liquid olestra giving greater aggregation than solid olestra. This is considered a beneficial aspect since increasing water-stable aggregation promotes soil particle hydrophobicity. The latter protects soils against erosion and crusting by raindrop impact. Olestra did not cause shrinkage when compared to sludge. Also, olestra assisted in reducing the tendency of soil to flow when wet. After examining the plastic limit, the data demonstrated that olestra had no effect on sludge, but sludge with olestra tended to reduce soil plasticity when wet. Olestra also increased the liquid holding capacity of the soils tested. Overall, there were no adverse effects when olestra was mixed with sludge and applied to the soil. All studies suggested that olestra did not harm the soil environment in any perceptible manner (Logan *et al.*, 1996).

The studies of Figge and Haigh-Baird (1997) suggest that mineralization rates varied considerably depending on the type of soil and the type of olestra. They noted that olestra underwent slow and limited mineralization in some German soils classified as Speyer (light sandy silt-high humus) and Borstel (light silt sand-low humus) and American soil classified as Madera (light silty sand-low humus) reaching only 6.9 to 18.4% mineralization after more than 400 days of incubation. The same olestra reached 35 to 52% mineralization in other types of soils of the German soil classified as Speicherkoog (loamy silt-high humus) as well as in the American soils classified as

Hollande (sandy loam-high humus), Thermal (light silty fine sand-low humus, and Uvaide (silty loam-moderate humus). They further suggested the larger amounts of solid olestra (i.e. with the more saturated fatty acids), the more likely it is to persist and possibly accumulate, following its application to soil. Laboratory findings cannot be directly applied to the field. It is possible that application of sewage sludge containing acclimatised microorganisms might promote mineralization of olestra in the soil (Figge and Schoeberl, 1989; in Figge and Haigh-Baird, 1997)). However, lower soil temperatures and soil dessication may reduce the rate of mineralization by reducing microbial activity and increasing the viscosity of the olestra (Figge and Haigh-Baird, 1997).

### 7.3 Contamination of plants with olestra

Although some microorganisms (Lee and Ventullo, 1996) are capable of degrading olestra, it is a slow process. Olestra can persist for some time depending on many, unknown factors (Logan *et al.*, 1996). Two studies were conducted to determine whether olestra is phytotoxic. In the study by Allgood (1994b), seeds of cucumbers, corn, soybeans, pinto beans and wheat were planted and grown for 21 days in soils containing 20% quartz sand with additions of olestra ranging from 0 to 930 mg of olestra /kg soil. At specified endpoints, the survival, dry root, shoot length, and weight were examined. The root weight of pinto beans was reduced at concentrations of olestra greater than 430 mg/kg of soil. From Allgood observations, there were no effects on any

of the plant species at levels of 224 mg or less of olestra /kg of sand. In a second study, Overcash and colleagues (1994) looked for phytotoxic effects on fescue, corn, soybean, and wheat, grown in soil alone (Norfolk loamy sand) and in mixtures of olestra and soil or soil with municipal sludge. Olestra was added at concentrations of 0 to 1,000 mg/kg soil and plants were grown during periods of 19 to 90 days depending on the plant species. Dissolved olestra in hexane was added to the mixtures with 20% of soil or soil with sludge. The findings showed no adverse effects on seed germination or plant growth at concentrations up to 1,000 mg/kg soil.

## DISCUSSION

For many years, food scientists have been searching for a dietary fat replacement. This replacement must have all the physical properties as fat and must make food palatable, crispy, tasty and be low in calories.

Simplex is a classic example of a protein-based fat substitute, which is used to make ice cream products, but it is not practical for use in cooking. Other synthetic fat replacers are not satisfactory as substitute fat-based type since those fat substitutes cannot withstand deep-frying temperatures. The latest fat replacer is olestra, which has physical and organoleptic properties closely resembling those of fats. Also, it can be used in a wide range of temperatures such as deep-frying foods.

To date many experiments have suggested that olestra tastes nearly as good as fat, does not interfere with absorption of common drugs, and does not change macronutrient and micronutrient absorption. Olestra interferes only with absorption of fat-soluble vitamins and this problem can be overcome by addition of those fat-soluble vitamins. So far, all the data suggest that olestra should not cause fat-soluble vitamin deficiencies.

In assessing the nutritional safety of consuming olestra, scientists have studied the effects of olestra in clinical laboratory animals such as mice, rats, pigs, rabbits, hamsters and dogs. Some of these reports concluded that there were no adverse effects, no toxicity

and no teratogenic, carcinogenic or genotoxic effects. Nonetheless, there are still some doubts and questions raised regarding the long-term effects of olestra.

After reviewing the literature on olestra, it appears that some questions still exist. Available data suggest that olestra in solid form has a half- life of more than 386 days in soil. This could be an environmental problem, particularly if olestra is consumed by a large segment of the population.

To attempt to solve this environmental problem, more basic research must be carried out to synthesize olestra that would remain resistant to pancreatic lipase while being sensitive to bacterial and fungal lipases in the soil. Soil samples should be screened for bacteria which are capable of degrading olestra. Such organisms would use olestra as a sole source of carbon and energy. Minimal agar plates (pour plates and spread plates), with olestra as sole carbon source, could be seeded with soil bacteria. Individual colonies, large and small, that appear can be tested for their ability to use olestra at different concentrations. Plates can be incubated with olestra and a mutagen to increase the number of soil bacteria able to use olestra. The largest colonies should be selected and the organisms that grow well on olestra should be tested in fluid thioglycollate medium for the ability to use olestra anaerobically. This fundamental research has not been done to date.

A better understanding of the gastrointestinal problems of sensitive individuals is needed. This is necessary because only when the intestinal problems are understood can appropriate remedies be applied. Individuals who ingest olestra over the long-term are

known to become deficient in fat-soluble vitamins. This problem can be overcome by ensuring that sufficient fat-soluble vitamins are added to such foods.

The long-term effects of olestra must be established using suitable animal models. To do so olestra must be used in the same way a toxic chemical would be used where it is studied at low, medium, and high concentrations.

The effect of olestra on individuals who are on drug or hormone therapy also needs to be examined. It is likely that high levels of olestra would prevent the entry of progestin/ estrogen in patients on hormone replacement therapy. Different levels of olestra should be used.

Other questions that need answers are: Does olestra interfere in alcohol adsorption or in alcohol consumption?

One final question regarding the use of olestra is important. Could olestra be useful in removing fat-soluble toxins such as mycotoxins? If so, this would give a needed boost to those who wish to make olestra available for human consumption on a large scale. With industry; however, there is always the suspicion that net profit wins over humanitarian efforts every time.

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